Exhibit A

STATE OF MISSOURI

CITY OF ST. LOUIS

IN THE CIRCUIT COURT OF THE CITY OF ST. LOUIS
STATE OF MISSOURI

LAVETA JORDAN; HEATHER HENK; JANNA LAATU; TYMESHA HUNT; JENNIFER BAGGETT; ASHLEY BAIRD; JESSICA BLAIR; MEAGAN BRADY; DARLA BROWN; CHRISTINE CLARK; CHRISTINE CLARK; AJIKE COATES; EBONY COX; CHERYL DENBOW; DAWN DIAZ; DEZIRE DIAZ; JENNIFER DISCHBEIN; ARLENE DOMINGUEZ; NATAHSA EBARB; NOELLE EDWARDS; STACEY EUELLS; RENEE EWING; SHALEENA FONUA; EUGENIA GALL; NICOLE GARZA; ILIANA GONZALEZ; TERESA GRAHAM; CANDACE GROF; AMY HEAD; SHERRI HELMS; TABATHA HICKS; JAVONDA HILL; TIFFANY HODGES; ANDREA HOGAN; ZENA MOORE HOLLINS; PENNY HOWARD; SHATRICA HOWARD; KRISTIN HUERTA; MARCI HUGHES; KELLY JOHNSON; JENNY JOHNSON; AMBER KAMBER; KIMBERLY KEARN; WENDY KELLEY; AMBER LAPLANT; KRISTIAN LEE; ELIZABETH LITTLE; JESSICA LOUDERMILK; JENNIFER MARECLE; STARLITA MCCALL; MARIAN MCGOWAN; AMY MENDEZ; ROBIN MEYERS; DAWN MIRUKA; JENNIFER MOTT; JANE NAGY; APRIL NEELY; MICHELLE NWANKWO; REGINA O'NEAL; DARYLYNE OSBORNE; LAKESHA OWENS; MELISSA PAGLIARINI; KELLI PARR; CRYSTAL PAXSON; PRINCILLA PEARSON; ASHELY PEEPLES; GRACELYN PRUITT; TIFFANY QUEEN; HILDA RAMIREZ-VILLEGAS; PATRICIA RANDELS; MONICA REINEIR; NANCY RIVERA; VANESSA RIVERA; ASYA RODGERS; ASHLEY ROGERS; TABITHA ROSS; AMY RUTAN; CRISTINA RUVALCABA; SOPHIA SILVA; HOLLIE SLEDGE; JESSICA STRICKLAND; TINA STRICKLAND; AMANDA SULLIVAN; KENESHA THOMAS; MARCELINA TURCIOS; TAMMY WARD; ERICA WARE; NINA WEAVER; FELICIA WEBER; MICHELLE WEEDMAN; LAVENA WILKERSON; MELISSA WILLIAMS; JOHNNIE WILLIAMS; CHARLI ZOVAK	)	CASE NO.: DIVISION NO.: JURY TRIAL DEMAND PETITION FOR DAMAGES

Plaintiffs

-vs

BAYER CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC., (F/K/A CONCEPTUS, INC.), BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER A.G

Defendants

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PETITION FOR DAMAGES

COMES NOW, the above named Plaintiffs by and through their undersigned counsel, and states as their Petition for Damages against BAYER CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC., (F/K/A CONCEPTUS, INC.), BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER A.G., (collectively herein referred to as "Bayer" or "Conceptus" or "Defendants") for personal injuries suffered as a result of being prescribed and implanted with the defective and unreasonably dangerous product Essure.

I. INTRODUCTION

1. This is an action for the serious and permanent injuries incurred by the Plaintiffs resulting from the promotion, sale, and distribution of an unreasonably dangerous and defective medical device product known as Essure.

2. Conceptus Inc. ("Conceptus") came up with the idea for the Essure device in 1998.

3. At that time, Conceptus was in hundreds of millions of dollars of debt.

4. The marketplace for permanent birth control was and is enormous. In 2007 Conceptus estimated that 700,00 American women undergo incisional tubal ligation each year. The market presented a huge business opportunity to Conceptus.

5. The Essure system consists of two metal coils that are implanted into a woman's fallopian tubes that expand and are intended to elicit tissue growth that causes blockage of the tubes and thus prevents conception.

6. The device was intended to be promoted as a simple solution to permanent birth control needs, and safer than all other permanent birth control options.

7. By the time FDA approved Essure for sale in 2002, it was Conceptus' only commercial product.

8. Conceptus relied entirely on the success of Essure to solve its massive debt problems and achieve profitability.

9. Essure was a unique contraceptive device and the first of its kind on the market.

10. As such, Conceptus knew that physicians and patients needed to trust the safety of the device for it to be accepted in the marketplace and compete with other, more established and traditional alternative methods of permanent birth control.

11. Conceptus knew that any apprehensions about the safety of the Essure device on the part of physicians or patients could devastate sales and lead to the complete failure of the company.

12. To promote the perceived safety of the device and gain market acceptance, Conceptus devised and implemented a scheme to defraud physicians and patients, by means of false and fraudulent pretenses, representations and concealment of material facts.

13. After Essure came onto the market, thousands of Essure patients complained of adverse events directly to Conceptus.

14. Conceptus knew that if those complaints made it to the FDA and became public knowledge, it would inevitably result in changes to the Essure label, its risk/benefit profile, related physician advice, and patient's decisions.

15. In short, Conceptus knew that if the true safety risks and consequences were known to the public, sales of the device would plummet.

16. As a result, Conceptus made a decision to hide these safety risks and consequences from the FDA and the public.

17. Thousands of women reported complaints associated with Essure directly to Conceptus.

18. Conceptus was obligated under federal law to report these complaints to the FDA.

19. Conceptus withheld the vast majority of those complaints.

20. At the same time, Conceptus conducted enormous and aggressive marketing campaigns that disseminated what they knew to be false and misleading statements pertaining to the convenience, safety and efficacy of the device.

21. Conceptus engaged in substantial, widespread and systemic false, misleading and illegal promotional activities to encourage physicians and patients to use the Essure device.

22. While Conceptus engaged in substantial, widespread and systemic false, misleading and illegal promotional activities it violated its duty owed to the physician and patients, in concealing and failing to warn the physicians and patients of the known serious increased risks and complications stemming therefrom.

23. Conceptus knew that the withholding of safety information and adverse events, as well as the dissemination of false and misleading statements pertaining to the Essure device was illegal.

24. In fact, the FDA cited Conceptus several times for withholding safety information.

25. Conceptus knew that manipulating the public's knowledge of safety risks associated with Essure exposed patients to serious dangers and greatly increased adverse risks.

26. Despite knowing of these dangers and the illegality of their behavior, Conceptus continued to carry out its false and unlawful marketing and promotional scheme.

27. These illegal efforts proved to be highly effective, leading to hundreds of millions of dollars in revenue for Conceptus, and an eventual buyout of the company by Bayer for approximately $1.1 billion in 2013.

28. Bayer continued illegally hiding the true safety risks of Essure.

29. Those same tactics could not continue working for Bayer.

30. In 2013, the FDA began promoting the use of the MedWatcher app, a system that allowed patients with complaints to report their problems directly to the FDA itself, as opposed to the manufacturer.

31. By that time, thousands of women adversely affected by the Essure device had formed a support group named "Essure Problems" on Facebook, a digital social network.

32. The group currently consists of over 28,000 members.

33. Conceptus and Bayer had been able to effectively silence their voices and conceal their complaints for years because the companies controlled what information did and did not make it to the FDA.

34. However, through the use of the MedWatcher app, in the Fall of 2013 these women began to stand up to Bayer and report their problems directly to the FDA.

35. At that point, Bayer knew Essure was wreaking havoc on the lives of thousands of women.

36. Bayer could have chosen to acknowledge the true weight of all of this safety information and stopped promoting the device.

37. But with over a billion dollars invested in Essure, Bayer chose to protect its investment and continue promoting the false impression that the device was safe.

38. Bayer knew that they could no longer hide complaints made through MedWatcher, because those reports originated with the FDA.

39. So Bayer began to employ new tactics to conceal and downplay the true safety risks of Essure.

40. Bayer carefully manipulated its reports to the FDA and presented false and misleading information.

41. Bayer did this in an effort to maintain the impression that the Essure device had a positive risk/benefit profile and guard sales.

42. The women affected by Essure and the Essure Problems group, however, would not let Bayer continue to mislead the FDA and more women.

43. They demanded that the FDA take meaningful action to investigate and evaluate the building scientific knowledge concerning Essure.

44. At their insistence, in September of 2015, the FDA convened a meeting of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee to hear concerns from experts and patients, and plan recommendations for the Essure device.

45. At the hearing, experts funded by the Essure Problems group testified as to the many safety problems they had begun to observe with the device.

46. Shortly after the hearing, researchers from Cornell University published a study in the British Medical Journal with devastating conclusions about the comparative safety profile of Essure.

47. The study compared thousands of women from New York State who had undergone either a traditional tubal ligation or received the Essure implant, and concluded that women receiving Essure were ten times more likely to require a corrective reoperation.

48. As a result of this study and the efforts of the Essure Problems group, the FDA finally took drastic action.

49. In early March of 2016, the FDA announced that it would require a detailed boxed warning and patient-decision checklist as part of the Essure warning label.

50. The FDA reserves boxed warnings, commonly referred to as “black box warnings”, for only the most serious adverse events and indicate the highest level of risk.

51. The patient-decision checklist requires that every potential Essure patient receive and sign a checklist specifically tailored to the risks associated with the device.

52. In November of 2016, the FDA approved the new Essure warning label, which better addresses the numerous risks and health problems associated with Essure.

53. In its current form, the “black box warning” specifically warns about the risks of device migration, organ perforation, allergic reactions, persistent pain, and the fact that surgery will be required if the device is to be removed for any reason.

54. The checklist specifically warns of device migration, perforation of organs, and other health problems caused by Essure that Conceptus and Bayer had been cited for hiding from the FDA and the public for years.

55. Now, women considering the device will have the chance to be fully informed of its true risks.

56. Conceptus and Bayer knowingly and purposefully concealed these risks for years.

57. Congress recently called for the removal of Essure from the market.

58. Spurred to action by the Essure Problems group, Pennsylvania Congressman Mike Fitzpatrick has been the leading voice in Congress on the issue.

59. On November 4 of 2015, Congressman Fitzpatrick introduced a bipartisan bill entitled the "E-Free Act" which would entirely ban sales of the Essure device.

60. Congressman Fitzpatrick stated that it was imperative that Bayer immediately end production of a product that poses such a danger to patient safety.

61. Unfortunately, Plaintiffs herein were not afforded the knowledge and warnings that would have informed and protected them.

II. PARTIES

A. Plaintiffs

62. Below is a list of each Plaintiff who is bringing her own case against Defendants:

63. Plaintiff Laveta Jordan is a citizen of Missouri and a resident of St. Louis, Missouri and was first injured in the City of St. Louis, Missouri as she was implanted with the Essure device during a procedure at the Barnes Jewish Hospital in St. Louis, Missouri.

64. Plaintiff Heather Henk is a citizen of Indiana and a resident of Covington, Indiana. Indiana is the location of Defendant's corporate headquarters.

65. Plaintiff Janna Laatu is a citizen of Pennsylvania and a resident of Belle Vernon, Pennsylvania. Pennsylvania is the location of Defendant's corporate headquarters.

66. Plaintiff Tymesha Hunt is a citizen of Delaware and a resident of Bridgeville, Delaware. Delaware is the location of Defendant's corporate headquarters.

67. Plaintiff Jennifer Baggett is a resident of High Ridge, Missouri.

68. Plaintiff Ashley Baird is a resident of Andrews, Texas.

69. Plaintiff Jessica Blair is a resident of Mount Vernon, Ohio.

70. Plaintiff Meagan Brady is a resident of Casa Grande, Arizona.

71. Plaintiff Darla Brown is a resident of Woodward, Oklahoma.

72. Plaintiff Christine Clark is a resident of Ratcliff, Arkansas.

73. Plaintiff Christine Clark is a resident of Vancouver, Washington.

74. Plaintiff Ajike Coates is a resident of Wetumpka, Alabama.

75. Plaintiff Ebony Cox is a resident of Harriet, Arkansas.

76. Plaintiff Cheryl Denbow is a resident of Cedar Hill, Missouri.

77. Plaintiff Dawn Diaz is a resident of Denver, Colorado.

78. Plaintiff Dezire Diaz is a resident of Colorado Springs, Colorado.

79. Plaintiff Jennifer Dischbein is a resident of Pontoon Beach, Illinois.

80. Plaintiff Arlene Dominguez is a resident of El Paso, Texas.

81. Plaintiff Natasha Ebarb is a resident of Rossville, Georgia.

82. Plaintiff Noelle Edwards is a resident of Liberty Township, Ohio.

83. Plaintiff Stacey Euells is a resident of Powder Springs, Georgia.

84. Plaintiff Renee Ewing is a resident of Genoa, Colorado.

85. Plaintiff Shaleena Fonua is a resident of Roy, Utah.

86. Plaintiff Eugenia Gall is a resident of Paragould, Arkansas.

87. Plaintiff Nicole Garza is a resident of Mount Enterprise, Texas.

88. Plaintiff Iliana Gonzalez is a resident of Bronx, New York.

89. Plaintiff Teresa Graham is a resident of Lancaster, California.

90. Plaintiff Candace Grof is a resident of Henderson, Nevada.

91. Plaintiff Amy Head is a resident of Fort Smith, Arkansas.

92. Plaintiff Sherri Helms is a resident of Warren, Ohio.

93. Plaintiff Tabatha Hicks is a resident of New Marshfield, Ohio.

94. Plaintiff Javonda Hill is a resident of Mesquite, Texas.

95. Plaintiff Tiffany Hodges is a resident of Pace, Florida.

96. Plaintiff Andrea Hogan is a resident of McDonough, Georgia.

97. Plaintiff Zena Moore Hollins is a resident of Fort Wayne, Indiana.

98. Plaintiff Penny Howard is a resident of Midland, Texas.

99. Plaintiff Shatrica Howard is a resident of Bloomington, Illinois.

100. Plaintiff Kristin Huertas is a resident of Copperas Cove, Texas.

101. Plaintiff Marci Hughes is a resident of Oak Park, Illinois.

102. Plaintiff Kelly Johnson is a resident of Pickerington, Ohio.

103. Plaintiff Jenny Johnson is a resident of Wheat Ridge, Colorado.

104. Plaintiff Amber Kamber is a resident of Santa Nella, California.

105. Plaintiff Kimberly Kearn is a resident of McCalla, Alabama.

106. Plaintiff Wendy Kelly is a resident of Pine Bluff, Arkansas.

107. Plaintiff Amber LaPlant is a resident of Niagara Falls, New York.

108. Plaintiff Kristian Lee is a resident of Lake Jackson, Texas.

109. Plaintiff Elizabeth Little is a resident of Scobey, Mississippi.

110. Plaintiff Jessica Loudermilk is a resident of North Lewisburg, Ohio.

111. Plaintiff Jennifer Marecle is a resident of Toledo, Ohio.

112. Plaintiff Starlita McCall is a resident of Columbus, Ohio.

113. Plaintiff Marian Mcgowan is a resident of Houston, Texas.

114. Plaintiff Amy Mendez is a resident of Eastlake, Ohio, Texas.

115. Plaintiff Robin Meyers is a resident of Olney, Texas.

116. Plaintiff Dawn Miruka is a resident of Vancouver, Washington.

117. Plaintiff Jennifer Mott is a resident of Hazel Green, Alabama.

118. Plaintiff Jane Nagy is a resident of Notasulga, Alabama.

119. Plaintiff April Neely is a resident of Amarillo, Texas.

120. Plaintiff Michelle Nwankwo is a resident of Easley, South Carolina.

121. Plaintiff Regina O'Neal is a resident of Escondido, California.

122. Plaintiff Darylyne Osborne is a resident of DeKalb, Illinois.

123. Plaintiff Lakesha Owens is a resident of Gainesville, Florida.

124. Plaintiff Melissa Pagliarini is a resident of Warwick, Rhode Island.

125. Plaintiff Kelli Parr is a resident of Monroeville, Ohio.

126. Plaintiff Crystal Paxson is a resident of Lebanon, Ohio.

127. Plaintiff Princilla Pearson is a resident of Taylor, Mississippi.

128. Plaintiff Ashley Peeples is a resident of Norwalk, Ohio.

129. Plaintiff Gracelyn Pruitt is a resident of Hector, Arkansas.

130. Plaintiff Tiffany Queen is a resident of St. Louis, Missouri.

131. Plaintiff Hilda Ramirez-Villegas is a resident of Chicago, Illinois.

132. Plaintiff Patricia Randels is a resident of Casper, Wyoming.

133. Plaintiff Monica Reineir is a resident of Belgrade, Montana.

134. Plaintiff Nancy Rivera is a resident of Joliet, Illinois.

135. Plaintiff Vanessa Rivera is a resident of Casselberry, Florida.

136. Plaintiff Asya Rodgers is a resident of Houston, Texas.

137. Plaintiff Ashley Rogers is a resident of Malvern, Ohio.

138. Plaintiff Tabitha Ross is a resident of Austin, Texas.

139. Plaintiff Amy Rutan is a resident of Lathrop, California.

140. Plaintiff Christina Ruvalcaba is a resident of Madera, California.

141. Plaintiff Sophia Silva is a resident of McAllen, Texas.

142. Plaintiff Hollie Sledge is a resident of Wonder Lake, Illinois.

143. Plaintiff Jessica Strickland is a resident of Zebulon, North Carolina.

144. Plaintiff Tina Strickland is a resident of Live Oak, Florida.

145. Plaintiff Amanda Sullivan is a resident of Colorado Springs, Colorado.

146. Plaintiff Kenesha Thomas is a resident of Houston, Texas.

147. Plaintiff Marcelina Turcios is a resident of Houston, Texas.

148. Plaintiff Tammy Ward is a resident of Marion, Ohio.

149. Plaintiff Erica Ware is a resident of St. Louis, Missouri.

150. Plaintiff Nina Weaver is a resident of Harrisburg, Pennsylvania.

151. Plaintiff Felicia Weber is a resident of Gouverneur, New York.

152. Plaintiff Michelle Weedman is a resident of Byrnes Mill, Missouri.

153. Plaintiff Lavena Wilkerson is a resident of Sarcoxie, Missouri.

154. Plaintiff Melissa Williams is a resident of Blaine, Minnesota.

155. Plaintiff Johnnie Williams is a resident of Columbus, Ohio.

156. Plaintiff Charli Zovak is a resident of Rogers, Arkansas.

B. Defendants

157. BAYER CORP. is a for-profit corporation incorporated in the state of Indiana with its principal place of business at 100 Bayer Rd. Building 4, Pittsburgh, PA 15205, and is a wholly-owned subsidiary of Bayer A.G. BAYER CORP. is a citizen of Pennsylvania and Indiana.

158. BAYER HEALTHCARE LLC is a for-profit corporation formed under the laws of the State of Delaware and is a wholly-owned subsidiary of Bayer A.G. BAYER HEALTHCARE LLC is a citizen of Delaware, Pennsylvania, New Jersey, Germany, and the Netherlands.

159. BAYER ESSURE, INC. (F/K/A CONCEPTUS, INC.) is a for-profit corporation incorporated in the state of Delaware, and is a wholly-owned subsidiary of Bayer A.G. and/or Bayer HealthCare LLC. On or about April 28, 2013, Conceptus, Inc. entered into an Agreement and Plan of Merger (the "Merger Agreement") with Bayer HealthCare LLC. On or about June 5, 2013, pursuant to the Merger Agreement, Conceptus, Inc. became a wholly-owned subsidiary of Bayer HealthCare LLC and/or Bayer A.G., and thereafter renamed "Bayer Essure Inc." For purposes of this Petition, Conceptus, Inc. and Bayer Essure Inc. are one and the same. As of April 21, 2016, Bayer Essure Inc.'s headquarters is located at 100 Bayer Boulevard, Whippany, New Jersey and Bayer Essure Inc.'s principal place of business is in New Jersey. BAYER ESSURE, INC. is a citizen of Delaware and New Jersey.

160. BAYER HEALTHCARE PHARMACEUTICALS, INC. is a for-profit corporation incorporated in the state of Delaware and is a wholly owned subsidiary of Bayer A.G. Bayer Healthcare Pharmaceuticals, Inc. has its principal place of business in New Jersey. BAYER HEALTHCARE PHARMACEUTICALS, INC. is a citizen of Delaware and New Jersey.

161. BAYER A.G. is a German for-profit corporation.

162. At all relevant times herein mentioned, Bayer authorized and directed and/or participated in the promotion and sale of Essure, when they knew, or with the exercise of reasonable care should have known, of the increased risks, hazards and unreasonably dangerous propensities, and thereby actively participated in the tortious conduct which resulted in the serious injuries to the Plaintiffs described herein.

163. There exists, and at all times herein mentioned, there existed, a unity of interest in ownership between the certain Defendants and other Defendants such that any individuality and separateness between them has ceased and these Defendants are the alter ego of the other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as any entity distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction fraud and/or would promote injustice.

164. At all times herein mentioned, the Bayer Defendants, and each of them, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling the Essure device. These products were for use by the Plaintiffs and Plaintiffs physicians. As such, each of the Bayer Defendants is individually, as well as jointly and severally, liable to the Plaintiffs for their damages.

165. The harm caused to Plaintiffs resulted from the conduct of one or various combinations of the Defendants, and through no fault of Plaintiffs. There may be uncertainty as to which one or which combination of Defendants caused the harm. Defendants have superior knowledge and information on the subject of which one or which combination of the Defendants caused Plaintiffs injuries.

166. Thus, the burden of proof should be upon each Defendant to prove that the Defendant has not caused the harms suffered by the Plaintiffs.

III. JURISDICTION AND VENUE

167. The Court has personal jurisdiction pursuant to § 506.500 R.S. Mo., over the Defendants because, at all relevant times, they have engaged in substantial business activities in the State of Missouri. At all relevant times, the Defendants transacted, solicited, and conducted business in Missouri through their employees, agents, and/or sales representatives, and derived

substantial revenue from such business in Missouri. Jurisdiction in this court is also proper because the defendants committed torts in whole or in part against Plaintiffs in Missouri. Further, there is no federal subject matter jurisdiction because no federal question is raised, and there is no diversity jurisdiction.

168. There is no federal diversity jurisdiction, because Plaintiff Janna Laatu and Defendant BAYER CORP. are both citizens of Pennsylvania. Additionally, Plaintiff Heather Henk and Defendant BAYER CORP. are both citizens of Indiana.

169. Likewise, there is no federal diversity jurisdiction because Plaintiff Tymesha Hunt and Defendant BAYER HEALTHCARE LLC are both citizens of Delaware. Additionally, Plaintiff Janna Laatu and Defendant BAYER HEALTHCARE LLC are both citizens of Pennsylvania. Further, there is no federal diversity jurisdiction because Plaintiff Tymesha Hunt and Defendant BAYER ESSURE INC. are both citizens of Delaware. There is also no federal diversity jurisdiction because Plaintiff Tymesha Hunt and Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. are both citizens of Delaware.

170. Venue is proper in this Court, pursuant to § 508.010(4) R.S. Mo., as Plaintiff Laveta Jordan is a citizen of Missouri and is a resident of St. Louis, Missouri and the conduct which gave rise to Plaintiff Laveta Jordan's action occurred in the City of St. Louis, Missouri, as she was first injured in the City of St. Louis, Missouri when she underwent the Essure procedure at the Barnes Jewish Hospital in St. Louis, Missouri.

171. The plaintiffs herein are all properly joined in this action pursuant to 507.040 R.S. Mo as they assert a right to relief under the same series of occurrences and questions of law and fact are common to all plaintiffs in this action.

IV. FACTS

a. DESCRIPTION OF ESSURE AND HOW IT WORKS

172. Essure is a Class III medical device manufactured, designed, formulated, tested, packaged, labeled, produced, constructed, assembled, marketed, advertised, promoted, distributed, and sold by Bayer.[1]

173. In April 2002, Conceptus, the original manufacturer of Essure, submitted its Premarket Approval Application to the United States Food and Drug Administration ("FDA") for the Essure system. The Essure system was approved by the FDA on November 4, 2002. At the time of approval, Essure was manufactured and marketed by Conceptus, Inc. (Bayer acquired Conceptus on June 5, 2013).[2]

174. Essure is considered a permanent form of female birth control and therefore is not intended to be removed.[3]

175. The Essure system consists of three components: (1) two micro-inserts (coils), (2) a disposable delivery system, and (3) a disposable split introducer. All components are intended for single use.

176. The Essure micro-inserts are constructed of a stainless steel inner coil, a dynamic outer coil made from a nickel and titanium alloy, called Nitinol, and a layer of polyethylene terephthalate, or polyester fibers, wound between the inner and outer coils.

177. Essure's disposable delivery system consists of a single handle containing a delivery wire, release catheter, and delivery catheter. The micro-inserts are attached to the delivery wire. The delivery handle controls the device, delivery, and release. Physicians are allowed to visualize this complicated process through the hysteroscopic (camera) equipment provided by Bayer.

178. During the Essure system implantation procedure, a physician inserts the Essure micro-inserts through the vagina and cervix and into the fallopian tubes via Defendants' disposable delivery system using a hysteroscope for guidance.

179. Once the physician has properly positioned the delivery system in the fallopian tube, the physician releases the micro-insert. When released, the micro-insert automatically expands to the contours of the fallopian tube to anchor into the fallopian tube permanently.

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[1] *See* "Essure Permanent Birth Control: Regulatory History," available online at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452270.htm

[2] *Id.*

[3] *See* "Essure Permanent Birth Control," available online at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/default.htm

180. After implantation and over a 3-month period, the PET fibers on the micro-inserts are supposed to elicit tissue growth around the coils, which causes bilateral occlusion (blockage) of the fallopian tubes. The build-up of tissue creates a barrier that keeps sperm from reaching the eggs, thus preventing conception.[4] During the 3-month time period, the woman must use another form of birth control while tissue in-growth occurs.

181. At 3-months following the procedure, the patient is to receive a "Confirmation Test" to determine whether the Essure micro-inserts have created a complete occlusion in each fallopian tube. The Confirmation Test used is a hysterosalpingogram ("HSG Test").

b. MEDICAL DEVICE REGULATORY FRAMEWORK

182. To understand the full scope of the allegations contained in this Complaint, a brief general background regarding the applicable FDCA provisions is warranted, as well as an application of those laws to the present case.[5]

183. The United States Food and Drug Administration ("FDA") is the federal agency of the United States of America that is charged with safeguarding the health and safety of the public by enforcing the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et seq. (2012) (the "FDCA").[6]

184. In 1976, Congress enacted the Medical Device Amendments of 1976 ("MDA") to extend the coverage of the FDCA to medical devices. The MDA was passed to protect patients with the idea that medical devices should be subjected to a rigorous approval process for specific indications before medical device manufacturers are allowed to market them. Therefore, the FDA has authority over drugs and medical devices under the FDCA and the MDA.

185. The MDA established three regulatory classes for medical devices. The three classes are based on the degree of control necessary to assure that the various types of devices are safe and effective according to user risk. Class I Medical Devices pose the least risk, whereas Class III Medical Devices pose the greatest risk to the users.[7]

186. Class I Medical Devices are subject to "general controls" such as labeling requirements.[8] Class II Medical Devices are subject not only to "general controls," but also to

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[4] *See* "Essure Permanent Birth Control," available online at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/default.htm

[5] Plaintiffs are not seeking to enforce these provisions in this action. Likewise, Plaintiffs are not suing merely because Medtronic's conduct violates these provisions. Rather Plaintiffs are alleging that Medtronic's conduct that violates these federal regulations, as well as the PMA obtained for Infuse®, also violates parallel state laws.

[6] The ultimate responsibility for the safety of a medical device rests with the Manufacturer.

[7] 21 U.S.C. § 360c(a)(1) (2012).

[8] 21 U.S.C. § 360c(a)(1)(A) (2012).

"special controls" such as "performance standards, post market surveillance, and patient registries."[9] If a device cannot be determined to provide a reasonable assurance of safety and effectiveness under Class I or II controls and is either marketed as a life supporting device or may cause an unreasonable risk of illness or injury, then it rises to the level of a Class III Medical Device.[10]

187. Class III Medical Devices are the most regulated. The MDA defines a Class III Medical Device as one that supports or sustains human life or is of substantial importance in preventing impairment of human health or presents a potential, unreasonable risk of illness or injury.[11] Class III Medical Devices pose the greatest risk of death or complications and include most implantable surgical devices.

188. Essure is a Class III device and received FDA's most stringent review prior to marketing, using the Pre-market Approval (PMA) process.[12]

i. Class III Medical Device Pre-Market Approval Requirements

189. Before a company can market a Class III Medical Device, the company is required to submit a premarket application to the FDA supported by data that provides the FDA with a reasonable assurance that the medical device is safe and effective for its intended use.[13] In order to show safety and effectiveness, the applicant is required to submit evidence to the FDA, typically in the form of clinical trial results.

190. A PMA application must contain certain information, which is critical to the FDA's evaluation of the safety and efficacy of the medical device at issue.

191. Once the FDA has approved a medical device through the PMA application process (such as Essure) the manufacturer/applicant is required to comply with the standards and conditions set forth in the PMA approval letter.[14]

192. A Class III device that fails to meet the Premarket Approval ("PMA") requirements after marketing is considered to be adulterated under § 501(f) of the Federal Food, Drug and Cosmetic Act ("FDCA") and cannot continue to be marketed.

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[9] 21 U.S.C. § 360c(a)(1)(B) (2012).
[10] 21 U.S.C. § 360c(a)(1)(C) (2012).
[11] *Id.* Bayer's Essure is a Class III Medical Device.
[12] *See* "Essure Permanent Birth Control: Regulatory History," available online at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452270.htm
[13] 21 U.S.C. § 360e(a)(2), § 360e(d)(1)(B)(iii), §360e(d)(2)(A) (2012).
[14] 21 C.F.R. § 814.80 (2012).

193. Essure's PMA was accompanied by an attachment setting forth the general "Conditions of Approval." Some of the notable conditions made available to the public via the FDA's website required Defendant to:

A) Conduct two Post-Approval Studies to: (1) gather five-year follow up information on the participants in the two premarket clinical trial patient cohorts (Phase 2 trial and Pivotal Trial) and (2) evaluate bilateral placement rate for newly trained physicians.[15]

B) Warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws.[16]

C) Submit a PMA supplement when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.[17]

D) Submit post-approval reports required under 21 C.F.R. § 814.84 at intervals of 1 year from the date of approval of the original PMA, which shall include: (1) a bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant: (i) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and (ii) reports in the scientific literature concerning the device.[18]

E) Submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" within 10 days after the applicant receives or has knowledge of information concerning: (1) any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and: (i) has not been addressed by the device's labeling; or (ii) has been addressed by the device's labeling but is occurring with unexpected severity or frequency; (2) any

[15] *See* "Essure Permanent Birth Control: Regulatory History," available online at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452270.htm

[16] *See* http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014a.pdf (The FDA specifically states that it does not evaluate information related to contract liability warranties).

[17] *see* http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014a.pdf

[18] *Id.*

significant chemical, physical or other change or deterioration in the device, or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling.[19]

F) Report to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer: (1) may have caused or contributed to a death or serious injury; or (2) has malfunctioned and such device or similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.[20]

194. The FDA made clear in the PMA order that "[f]ailure to comply with the conditions of approval invalidated this approval order and commercial distribution of a device that is not in compliance with these conditions is a violation of the act."[21]

ii. General Reporting Duties to the FDA are Required After the PMA Process

195. A medical device manufacturer's obligations do not end with the FDA's Premarket Approval ("PMA") process.

196. Under federal law a medical device manufacturer has a continuing duty to monitor their product after premarket approval and to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product.[22]

197. Accurate reporting of adverse events is essential, as it serves to notify the public that a potential problem with the device exists, and can prompt an informed person or organization to develop a solution. The FDA and others, including the public, rely upon accurate and timely reporting of adverse events. Post-market surveillance by FDA is hampered when mandatory reporting terminology is not clear, accurate, and consistent.

198. Manufacturers are required to report to the FDA "no later than 30 calendar days after the day: the manufacturer receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device" marketed by the manufacturer:

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[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] 21 C.F.R. § 803.50(a) (2012); 21 U.S.C. § 360i(a) (2012).

A) may have caused or contributed to death or serious injury; or

B) has malfunctioned in a manner that would likely "cause or contribute to a death or serious injury" if it recurred.[23]

199. "Becomes aware" means that an employee of the entity required to report has acquired information that reasonably suggests a reportable adverse event has occurred.[24] A manufacturer is considered to have become aware of an event when any of its employees becomes aware of a reportable event that is required to be reported within 30 calendar days.[25] A manufacturer is also considered to have become aware of an event when any of its employees with management or supervisory responsibilities over persons with regulatory, scientific, or technical responsibilities, or whose duties relate to the collection and reporting of adverse events, becomes aware, from any information, including any trend analysis, that a reportable MDR event or events necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.[26]

200. "Serious injury" is defined as an injury or illness that: (1) is life-threatening, (2) results in permanent impairment of a body function or permanent damage to a body structure, or (3) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. Permanent means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.[27]

201. "Malfunction" is defined as a failure of a device to meet its performance specifications or otherwise to perform as intended.[28] Performance specifications include all claims made in the labeling for the device.[29] The intended performance of a device refers to the intended use for which the device is labeled or marketed.[30]

202. A malfunction should be considered reportable if any one of the following is true:

(1) the chance of a death or serious injury resulting from a recurrence of the malfunction is not remote;

(2) the consequences of the malfunction affect the device in a catastrophic manner that may lead to a death or serious injury;

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[23] 21 C.F.R. § 803.50(a); *see also* 21 U.S.C. § 360i(a) (further detailing the post approval reporting requirements applicable to device manufacturers).
[24] *See* 21 C.F.R. § 803.3(b) (2012).
[25] *Id.*
[26] *See* 21 C.F.R. § 803.3(b)(2) (2012).
[27] 21 C.F.R. § 803.3(w) (2012).
[28] 21 C.F.R. § 803.3 (2012).
[29] *Id.*
[30] *Id.*

(3) the malfunction causes the device to fail to perform its essential function and compromises the device's therapeutic, monitoring or diagnostic effectiveness which could cause or contribute to a death or serious injury, or other significant adverse device experiences. The essential function of a device refers not only to the device's labeled use, but for any use widely prescribed within the practice of medicine; or

(4) the malfunction involves a long-term device implant that would prevent the implant from performing its function.[31]

203. Reporters do not need to assess the likelihood that a malfunction will recur. The regulation assumes that if a malfunction has occurred once, the malfunction will recur.[32]

204. "*Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated*, unless such investigation has already been performed for a similar complaint and another investigation is not necessary."[33]

205. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate."[34]

206. "Any complaint that represents an event which must be reported to FDA under part 803 of the Medical Device Reporting regulations shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by 820.198(e), records of investigation under this paragraph shall include a determination of: (a) [w]hether the device failed to meet specifications; (b) [w]hether the device was being used for treatment or diagnosis; and (c) [t]he relationship, if any, of the device to the reported incident or adverse event."[35]

207. Manufacturers, such as Defendant, may receive device-related complaints from information from many different sources, including telephone calls or other verbal communication,

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[31] *See* "Medical Device Reporting For Manufacturers," available online at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094529.htm#al

[32] *Id.*

[33] 21 C.F.R. § 820.198(C) (2012) (Emphasis added).

[34] 21 C.F.R. § 820.198(b) (2012).

[35] 21 C.F.R. § 820.198(d) (2012).

FAX transmissions, written correspondence, sales representative reports, service representative reports, scientific articles (literature), internal analyses, and legal documents.[36]

208. Additionally, manufacturers of Class III Medical Devices are required to make periodic reports to the FDA regarding approved devices, which must include summaries of:

A) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant; and

B) reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant.[37]

As presented below, Defendants failed to comply with several of the aforementioned conditions of their PMA Order and federal regulations governing medical device manufacturer reporting requirements.

iii. A Manufacturer Must Follow Current Good Manufacturing Practices

209. Under 21 C.F.R. § 820.1(a) of the Quality System (QS) Regulation for Medical Devices, current good manufacturing practice (CGMP) requirements are set forth in this quality system regulation. The requirements govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The requirements are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the FDCA.[38] This part establishes basic requirements applicable to manufacturers of finished medical devices.

210. 21 C.F.R. § 820.5 (2012) "Quality Systems", the FDA regulations state, "Each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part."

211. 21 C.F.R. § 820.30(i) (2012): "Design controls" states (i) Design changes. Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.

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[36] *See* "Draft Guidance for Industry and Food and Drug Administration Staff: Medical Device Reporting for Manufacturers" available online at: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm359566.pdf

[37] 21 C.F.R. § 814.84(b)(2) (2012).

[38] *See* 21 C.F.R. § 820.1(a) (2012).

212. 21 C.F.R. § 820.30(g) (2012): Design validation means establishing by objective evidence that device specifications conform with user needs and intended use(s) and "shall include testing of production units under actual or simulated use conditions."

213. 21 C.F.R. § 820.22 (2012): "Quality Audit" states: "Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system."

214. 21 C.F.R. § 820.160(a) (2012): "Distribution" states: "Each manufacturer shall establish and maintain procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed". In other words, a manufacturer is only permitted to distribute a medical device that is approved.

215. 21 C.F.R. § 820.170(a) (2012): "Installation" states: Each manufacturer of a device requiring installation shall establish and maintain adequate installation and inspection instructions, and where appropriate test procedures. Instructions and procedures shall include directions for ensuring proper installation so that the device will perform as intended after installation. The manufacturer shall distribute the instructions and procedures with the device or otherwise make them available to the person(s) installing the device.

216. 21 C.F.R. § 803 (2012), states: Manufacturers must include information that is reasonably known to the manufacturer, timely make Medical Device Reporting ("MDR") submissions, define the procedures for implementing corrective and preventative actions, and review sampling methods for adequacy of their intended use.

217. 21 C.F.R. § 820.100 (2012) "Corrective and Preventive Action" states: Manufacturers shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

(1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;

(2) investigating the cause of nonconformities relating to product, processes, and the quality system;

(3) identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

(4) verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device; and

(5) implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems.[39]

218. The purpose of the corrective and preventive action subsystem is to collect information, analyze information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence.[40] Implementing corrective and preventive actions are essential in dealing effectively with product and quality problems, preventing their recurrence, and preventing or minimizing device failures.

219. As presented below, Defendants failed to comply with several of the aforementioned conditions of their PMA Order and federal regulations governing medical device manufacturing processes.

iv. PMA Supplements For Labeling Changes

221. Any changes the manufacturer believes could affect the safety and effectiveness of the device must be submitted via a "PMA Supplement," to the FDA for approval.[41]

222. While the burden for determining whether a supplement is required is primarily on the PMA holder, changes for which an applicant shall submit a PMA supplement include labeling changes if they affect the safety or effectiveness of the device.[42]

223. Most changes to the labeling of a device after premarket approval require prior FDA approval, but a manufacturer may place into effect:

(1) "[l]abeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association;

(2) "[l]abeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device, and;

(3) "[l]abeling changes that delete misleading, false, or unsupported indications."[43]

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[39] 21 C.F.R. § 820.100 (2012).
[40] *See* http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm170612.htm
[41] 21 U.S.C. § (a) (2012).
[42] *Id.*
[43] *Id.*

224. Under those regulations, the manufacturer is required to notify the FDA of "Changes Being Effected" (CBE) to a device's labeling.

v. The FDA Prohibits Misleading Or False Promotion And Marketing

225. Under the FDCA and FDA's implementing regulations, labeling, promotional advertisements, and making claims about medical devices are deemed misleading if they fail to disclose certain information about the product's risks.

226. Generally, to comply with the FDCA and FDA's implementing regulations, and therefore the PMA, such promotional pieces: (a) Cannot be false or misleading in any particular;[44] (b) Must reveal material facts about the product being promoted, including facts about the consequences that can result from use of the product as suggested in the promotional piece.[45]

227. The FDA regulates the manufacture, sale, and distribution of medical devices in the United States under the authority of the FDCA. This authority includes oversight of labeling and advertising for all medical devices.[46]

228. A medical device shall be deemed to be misbranded if it's labeling is false or misleading in any particular.[47] Labeling or advertising may be considered misleading if it fails to reveal material facts about the product being promoted, including facts about the consequences that can result from use of the product as suggested in a promotional piece.[48]

229. Defendant's PMA approval letter for Essure specifically states that the FDA "[d]oes not evaluate information related to contract liability warranties, however [Defendant] should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws."[49]

vi. Violations of Federal Statutes or FDA Regulations Void the Federal Preemption Defense

230. There is a presumption against federal preemption of state laws that operate in traditional state domains.[50] "Throughout our history the several States have exercised their police powers to protect the health and safety of their citizens. States traditionally have had great latitude

[44] 21 U.S.C. §352(a) (2012).
[45] 21 U.S.C. § 321(n) (2012); 21 C.F.R. § 1.21(2012).
[46] *See* 21 U.S.C. § 352(a), (n), (q), & (r) (2012).
[47] 21 U.S.C. § 352(a) (2012).
[48] *See* 21 U.S.C. § 321(n) (2012).
[49] *See* http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014a.pdf
[50] *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons."[51]

231. "Nothing in § 360k denies [the states] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements."[52]

232. As the Supreme Court held in *Riegel v. Medtronic, Inc*., "State requirements are preempted under the MDA only to the extent that they are "different from, or in addition to" the requirements imposed by federal law.[53] Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case "parallel," rather than add to, federal requirements."[54]

233. "The idea that Congress would have granted civil immunity to medical device manufacturers for their violations of federal law that hurt patients is, to say the least, counterintuitive."[55]

234. "Medical device manufacturers who subject their Class III devices to the rigorous premarket approval process are protected by federal law from civil liability so long as they comply with federal law. That protection does not apply where the patient can prove that she was hurt by the manufacturer's violation of federal law."[56]

235. Claims for failure to warn are not preempted. "Failure to warn claims are neither expressly nor impliedly preempted by the MDA to the extent that this claim is premised on [the defendant manufacturer]'s violation of FDA regulations with respect to reporting [adverse outcomes] caused by the device."[57]

236. In *Stengel v. Medtronic, Inc*., the Supreme Court issued an Order inviting the Solicitor General to submit an Amicus Brief expressing the views of the United States. According to the Solicitor General, only device-specific federal requirements have preemptive force while "by contrast FDA's general manufacturing and labeling regulations do not have preemptive force."[58]

237. The Solicitor General stated that "federal requirement[s] are applicable to the device within the meaning of Section 360k(a)(1) only when they are applicable to the device in question

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[51] *Id.* at 475.
[52] *Id.* at 495.
[53] 21 U.S.C. § 360k(a)(1).
[54] *Riegel v. Medtronic*, 552 U.S. 312, 330 (2008).
[55] *Bausch v. Stryker Corp*., 630 F.3d 546, 549-550 (7th Cir. 2010). See also *Bausch* quoted with approval by the 9th Circuit in *Stengel v. Medtronic, Inc*., 704 F.3d 1224, 1226 (9th Cir. 2013) (*en banc*).
[56] *Id.* at 550 (italicized emphasis original).
[57] *Hughes v. Boston Scientific Corp*., 631 F.3d 762, 776 (5th Cir. 2011).
[58] U.S. Amicus Br. at 9, *Stengel v. Medtronic, Inc*., 704 F.3d 1224, 1226 (9th Cir. 2013).

and, in accordance with FDA regulations, only when they are specific counter part regulations or specific to a particular device."[59]

238. This reasoning led the Solicitor General to the conclusion that "[i]f a state requirement were preempted absent a specific federal requirement that reflects FDA's weighing of competing considerations on the same subject and specific to the device, the MDA would have the ironic effect of providing less public protection from unsafe and ineffective medical devices that pre-MDA law.[60]

239. In *Stengel*, and similarly in this complaint, the alleged conduct of the petitioner was governed by general manufacturing and labeling regulations applicable to all medical devices and not the device's pre-market approval.

240. It is the opinion of the Solicitor General that respondents' failure to warn claims escaped express preemption because "such a claim implicates no preemptive device-specific federal requirement."[61]

241. In summary, while manufacturers who comply with federal law may be entitled to certain protections, those who violate federal law are not entitled to preemption of state laws/immunity for their tortuous conduct and in fact are liable for their conduct that violates federal law.

c. CONCEPTUS DEPENDED SOLELY ON ESSURE SALES TO FIX THEIR PROBLEMS WITH MASSIVE DEBT AND ACHIEVE PROFITABILITY

242. Conceptus accumulated hundreds of millions of dollars in debt throughout its existence, never achieved profitability, and looked to sales of the Essure product as the sole solution.

243. By the end of 2007, Conceptus had an accumulated deficit of $235.2 million.

244. By the end of 2012, after all of its concerted sales efforts, Conceptus still had an accumulated deficit of $154.9 million.[62]

245. By that time, Conceptus had been in a cumulative net loss position for twenty years, since its inception.[63]

246. Conceptus stated that it would remain in an accumulated deficit position unless Essure sales grew large enough to offset its expenses.[64]

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[59] *Id.* at 8-9 (internal citations omitted).
[60] *Id.* at 11 (internal citations omitted).
[61] *Id.* at 7 (internal citations omitted).
[62] *See* http://www.sec.gov/Archives/edgar/data/896778/000119312513098624/d444338d10k.htm#toc
[63] *See* http://www.sec.gov/Archives/edgar/data/896778/000119312513098624/d444338d10k.htm#toc
[64] *Id.*

247. Beginning in 1998, Conceptus focused solely on the design, development, and clinical testing of Essure.

248. By 2002, Conceptus' revenue was derived almost entirely from the sale of Essure to physicians.

249. By 2007, Essure was Conceptus' only commercial product. Conceptus was entirely dependent on sales of the Essure device to survive, as they accounted for all of the company's revenues.[65]

250. That year, Conceptus stated that if the Essure device did not achieve acceptance among physicians and patients, the company would fail to sustain profitability.[66]

d. MANIPULATING SAFETY INFORMATION ALLOWED CONCEPTUS TO BECOME A VIABLE COMPANY

251. In order to profit from Essure and survive, Conceptus needed to convince physicians and women that the device was safe.

252. Because Essure is a wholly unique and new form of birth control, Conceptus did not compete with other similar products for share of an existing market.

253. Instead, Conceptus needed to create a new market for its product.

254. Physicians and women needed to accept the safety of Essure before there could be a demand for it.

255. Therefore, apprehensions about the device's safety have always been the biggest barrier to its success.

256. In 2007, Conceptus stated that if the Essure system did not achieve acceptance among physicians and patients, the company would fail to sustain profitability.[67]

257. Conceptus' committed all of its resources to persuading physicians and patients to accept the Essure device as a safe method of birth control.

258. Throughout its entire history, Conceptus marketed Essure aggressively through the use of public relations and targeted advertising in order to create acceptance of the device among general practitioners, women and the broader medical community.[68]

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[65] *See* http://www.sec.gov/Archives/edgar/data/896778/000110465907007326/a07-3143_18k.htm
[66] *See* http://www.wikinvest.com/stock/Conceptus_(CPTS)/Filing/10-K/2008/F2331313
[67] *See* http://www.wikinvest.com/stock/Conceptus_(CPTS)/Filing/10-K/2008/F2331313
[68] *See* http://www.sec.gov/Archives/edgar/data/896778/000089161804000719/f96941e10vk.htm

259. In April of 2003, Conceptus introduced Essure at the annual conference of the American College of Obstetricians and Gynecologists and offered two presentations as well as a Continuing Medical Education accredited symposium with Essure as the main topic.[69]

260. In June of 2003, Conceptus sent direct mail to 500,000 women, not physicians, in the Atlanta and Chicago areas.

261. The direct mail campaign encouraged those women to contact Conceptus' call centers who then referred the women to a physician offering Essure in her area.[70]

262. Conceptus also ran numerous regional advertisements in a variety of magazines, such as *Parents* and *Self*.[71]

263. Conceptus continuously fought to achieve market acceptance for Essure.

264. In 2008, Conceptus targeted women directly again in a marketing campaign that incorporated print media, radio and television advertising. The company claimed that the campaign was meant to drive patient awareness and increase physician office utilization.[72]

265. Conceptus also employed a robust sales force whose primary goals were to persuade a growing base of physicians to offer the device.[73]

266. Conceptus repeatedly treated its warning label as a tool to promote market acceptance and manipulated it to achieve those goals.

267. In 2008, Conceptus stated that it intended to make labeling improvements to Essure in order to increase the adoption of the Essure procedure.[74]

268. At one point, Conceptus' CEO described certain adequate warning information as merely a barrier to more success in sales.

269. Despite mounting complaints of allergenic reactions to Essure, in 2011 Conceptus drastically altered the warning label and removed sections that encouraged women to confirm their tolerance to nickel by use of a skin test.

270. Conceptus did not change anything about the device itself or its nickel contents.

271. Afterward, the president and CEO of Conceptus stated that the label change would strengthen the company's standing in the permanent birth control market by diminishing Essure's biggest competitive disadvantage.

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[69] *Id.*
[70] *Id.*
[71] *Id.*
[72] *See* http://www.wikinvest.com/stock/Conceptus_(CPTS)/Filing/10-K/2008/F2331313
[73] *See* http://www.sec.gov/Archives/edgar/data/896778/000119312513098624/d444338d10k.htm
[74] *See* http://www.wikinvest.com/stock/Conceptus_(CPTS)/Filing/10-K/2008/F2331313

272. Conceptus then reaffirmed its ultimate goal of gaining market acceptance by stating its intentions to aggressively present the change to the OB/GYN community. The company planned to especially target those physicians who were promoting other methods of birth control because of potential safety issues with the Essure device.

e. CONCEPTUS AND BAYER CONTINUOUSLY SPREAD FALSE AND MISLEADING INFORMATION TO ALTER PERCEPTIONS OF ESSURE'S SAFETY RISKS

273. Conceptus and Bayer advertised, promoted and marketed on its website, in its print and/or video advertisements, brochures and fact sheets the following representations about Essure:

A) The Essure patient brochure stated that Essure was the "only FDA approved female sterilization procedure to have zero pregnancies in the clinical trials". However, there were actually four pregnancies during the clinical trials and five pregnancies during the first year of commercial experience. Between 1997 and 2005, there were 64 pregnancies reported to Defendants. Additionally, there have been 631 reports of pregnancies according to the FDA of December 31, 2015. Furthermore, a recent study indicates that women implanted with Essure have a *ten times* greater risk of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost four times greater. Defendants concealed this information from Plaintiffs and Plaintiffs' physicians, yet promoted Essure as a more effective form of permanent sterilization than a tubal ligation.

B) The Essure website, print advertising, and patient brochure describes Essure as "worry free," and is a "simple procedure performed in your doctor's office" that takes "less than 10 minutes" and "requires no downtime for recovery" and "Essure eliminates the risks, discomfort, and recovery time associated with surgical procedures". However, Defendants actively concealed and failed to report complaints of perforations and pain, which occurred as a result of the Essure procedure. Additionally, Essure is not worry free because there is an increased risk that the Essure implants will cause women serious, life-altering complications including but not limited to debilitating pain, heavy bleeding necessitating medication and/or additional surgical intervention, allergic reactions (including but not limited to rashes, itching, bloating, swelling, headaches, tooth-loss, and hair loss), autoimmune disorders, dyspareunia, hysterectomy, and other complications.

C) The Essure website, print advertising, and patient brochure stated, "the Essure inserts stay secure, forming a long protective barrier against pregnancy. They also remain visible outside your tubes, so your doctor can confirm that they're properly in place". However, the micro-inserts do not necessarily remain securely in the fallopian tubes and can migrate and be expelled by the body, as evidenced by the over 850 reports of device migration as of December 31, 2015.[75]

D) The Essure website, print advertising, and patient brochure stated, "the Essure inserts are made from the same trusted, silicone free material used in heart stents". However, the micro-inserts are not made from the same material as heart stents and do not elicit tissue growth. The micro-inserts are made of PET fibers, which trigger inflammation and scar tissue growth. PET fibers degrade and leach carcinogens when placed in temperatures over 65 degrees, and the human body stays at about 98 degrees. As such, PET fibers are not designed or manufactured for use in human implantation. However, the PET fibers are made of the same materials as the PVT material in some vaginal meshes, which have a high rate of expulsion.

E) The Essure website, print advertising, and patient brochure stated, "Essure eliminates the risks, discomfort, and recovery time associated with surgical procedures." However, Essure does not eliminate the risks, discomfort, and recovery time associated with surgical procedures (i.e. tubal ligations) because many women who undergo the Essure procedure, including Plaintiffs, have never and will never fully recover from the Essure implant procedure, which has caused them serious, life-altering complications including but not limited to debilitating pain, heavy bleeding necessitating medication and/or additional surgical procedures, allergic reactions (including but not limited to rashes, itching, bloating, swelling, headaches, tooth-loss, and hair loss), autoimmune disorders, dyspareunia, hysterectomy, and other complications.

F) The Essure website, print advertising, and patient brochure stated, "Essure is the most effective permanent birth control available, even more effective than tying your tubes or a vasectomy" or words to that effect. Yet, Defendants' SEC Form 10-

[75] *See* http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452254.htm

k filing shows that Defendants never did a comparison to a vasectomy or tubal ligation. Specifically, Defendants stated they "did not conduct a clinical trial to compare the Essure procedure to laparoscopic tubal ligation."[76]

G) The Essure website claims "correct placement…is performed easily because of the design of the micro-insert". However, Defendants admitted that placement of the device requires a "skilled approach" and admitted that even their own experts in hysteroscopy failed to place the micro-inserts in one out of seven clinical participants.

274. Plaintiffs and Plaintiffs' implanting physicians relied on these representations by Conceptus and Bayer in recommending and undergoing the Essure procedure.

275. Conceptus and Bayer advertised, promoted and marketed on its websites, in its print and/or video advertisements, brochures, and fact sheets the following about physicians performing the Essure procedure, while failing to report the actual material facts:

A) "[p]hysicians must be signed-off to perform Essure procedure". However, Defendants failed to adequately train the implanting physician and "signed off" on the implanting physician who did not have the requisite training.

B) "An Essure trained doctor inserts spring-like coils, called micro-inserts". However, the implanting physician who implanted the device was not adequately trained.

C) "The Essure training program is a comprehensive course designed to provide information and skills necessary to select appropriate patients, perform competent procedures and manage technical issues related to the placement of Essure micro-inserts for permanent birth control". However, Defendants failed to adequately train the implanting physician.

D) "[i]n order to be trained in Essure you must be a skilled operative hysteroscopist. You will find the procedure easier to learn if you are already proficient in operative hysteroscopy and management of the awake patient. If your skills are minimal or out of date, you should attend a hysteroscopy course before learning Essure". However, Defendants "signed off" on physicians who were not skilled operative hysteroscopists, in order to monopolize and capture the market, including the implanting physician.

[76] Conceptus, Inc., Annual Report (Form 10-k) (Mar. 15, 2004).

E) "[i]n order to be identified as a qualified Essure physician, a minimum of one Essure procedure must be performed every 6-8 weeks". However, Defendants "signed off" on "Essure physicians" who did not perform the procedure every 6–8 weeks.

F) "[t]he PET fibers are what caused the tissue growth," and Essure "works with your body to create a natural barrier against pregnancy". However, during a PMA meeting with the FDA in 2002, Defendants represented that the trauma caused by the expanding coil hitting the fallopian tubes is what causes the inflammatory response of the tissue.

276. Plaintiffs and Plaintiffs' implanting physicians relied on these representations by Conceptus and Bayer in recommending and undergoing the Essure procedure.

f. CONCEPTUS AND BAYER HAVE ALWAYS KNOWN THAT ESSURE IS DANGEROUS

i. Conceptus Was Wrought With Early Regulatory Violations

277. From the beginning of the sale of the Essure device, Conceptus has repeatedly been cited by regulatory authorities for continuous violations that impacted patient safety.

278. In July of 2002, the FDA conducted a Directed PMA Data Inspection/Audit of Conceptus. At the conclusion of the inspection, the FDA inspector cited Conceptus for failing to report adverse events identified by patients during unscheduled visits in the data submitted for the Essure PMA.

279. In June and July of 2003, the FDA conducted a Post Market Approval Inspection of Conceptus. The FDA cited Conceptus for failing to adequately analyze all quality data sources to identify existing and potential causes of non-conforming product and other quality problems, and failing to follow procedures for the control of products that do not conform to specifications.

280. In June of 2008, the California Department of Public Health, Medical Device Safety Section ("CDPH"), conducted an inspection of Conceptus' location in Mountain View, California. The CDPH issued a Notice of Violation to Conceptus for failing to obtain a valid license to manufacture medical devices and failing to maintain procedure for inventory transfer.

ii. Conceptus Knew About A Myriad Of Manufacturing Problems

281. Subsequent to obtaining its CPMA, Conceptus became aware of potential quality and failure modes associated with the Essure devices. For example, Conceptus became aware that the following failures could occur with the device and lead to adverse consequences for the patient:

A) The stainless steel used in the device became unpassivated, which can cause the device to rust;

B) the nitinol could have a nickel rich oxide which the body attacks;

C) the no lead solder could in fact have trace lead in it;

D) the Galvanic action between the metals used to manufacture Essure, which causes the encapsulation of the product within the fallopian tubes, could be a continuous irritant to some patients;

E) the nitinol in the device can degrade due to High Nickel Ion release, increasing the toxicity of the product for patients;

F) latent manufacturing defects such as cracks, scratches, and other disruption of the smooth surface of the metal coil, may have existed in the finished product, causing excess nickel to leach into the surrounding tissues after implantation;

G) PET fibers degrade at 65 degrees, therefore considerable degradation is expected at 98 degrees in the human body and degradation products of the PET used in the implant can be toxic to patients, inciting both chronic inflammation and possible autoimmune issues;

H) the mucosal immune response to nickel is different than the immune response in non-mucosal areas of the body;

I) there was an inadequate solder joint between the inner and outer coils of the micro-insert which can cause the micro-insert to fracture/break apart, and which Bayer admits is or could be a reason for device breakage, and;

J) the central axis was not fully adhered to the spring which can cause the micro-insert to fracture/break apart, and which Bayer admits is or could be a reason for device breakage.

iii. Conceptus Concealed Thousands of Migration and Perforation Reports From the FDA

282. Conceptus knew of thousands of instances wherein the Essure device had migrated in a woman or perforated a woman's organs, failed to report all of them, and then fought the FDA on its reporting obligations once the agency discovered the problem.

283. In the years before 2011, Conceptus had accumulated thousands of reports from women that their devices had migrated throughout their bodies or punctured one of their organs.

284. To protect the marketability of the device, Conceptus chose not to report the vast majority of them.

285. Then, in December of 2010 the FDA conducted a "for cause" inspection of Conceptus and its reporting procedures.

286. At the conclusion of the inspection, the FDA inspector cited Conceptus for four conditions which he found objectionable and/or violations of the FDCA and federal regulations.

287. Three of the four objectionable conditions pertained to Medical Device Reporting deficiencies and/or violations and included:

A) Conceptus' failure to submit Medical Device Reporting ("MDR") determinations to the FDA within 30 days for reports of a serious injury involving the Essure device including 2 (two) reports of bowel perforation, and 1 (one) report of pain and the Essure device breaking into pieces immediately following implant;

B) Conceptus' failure to submit MDR's to the FDA within 30 days for reports of a serious injury involving the Essure device including, but not limited to 5 (five) reports of the Essure coils perforating the fallopian tubes and penetrating the peritoneal cavity; and

C) Conceptus' failure to include a failure mode for perforation itself and for the Essure micro-inserts migrating into the peritoneal cavity in their latest Risk Analysis Design FMEA for Essure, despite having documented at least 508 complaints of perforation between January 1, 2009 and December 8, 2010, and at least 177 complaints of perforation with the micro-insert was found in the peritoneal cavity between January 1, 2009 and January 4, 2011.

288. Specifically, the FDA inspector discovered that Conceptus was not reporting complaints of Essure coils being seen inside the patients' abdominal cavity and not opening a corrective and preventative action ("CAPA") when they became aware of these complaints.

289. The FDA discovered that Conceptus submitted Medical Device Reports ("MDRs") and reported complaints of the coils migrating into the peritoneal or abdominal cavity only if the patient was complaining of pain and a second procedure was required to remove the device.

290. Conceptus concealed such complaints if the coil was subsequently removed during a laparoscopic tubal ligation surgery that was performed due to a failure of occlusion of the fallopian tubes.

291. The FDA inspector demanded that Conceptus report these incidents because a migrated coil was inherently likely to lead to an injury. Conceptus' own complaint files contained hundreds of instances where this condition led to a serious complication.

292. Conceptus did not agree with FDA's position that physicians and women had a right to know about all dangerous events associated with the device.

293. Instead, Conceptus officials attempted to persuade the FDA inspector that they should not be forced to report such adverse events and make them publicly available.

294. Conceptus officials argued that a coil falling out of the fallopian tube was not technically a “malfunction" of the device, and therefore it did not need to be reported.

295. The FDA inspector explained that because the coil was designed to remain inside the fallopian tube, a coil that migrates out of the fallopian tube represents a situation where the Essure device is not functioning as it was designed and intended.

296. There was no medical reason to withhold this information from the public. Conceptus concealed these reports specifically to mislead physicians and women about the safety of the Essure device.

297. The size and scope of Conceptus' failure to report adverse events up until that time was enormous.

298. Just between January 1, 2008 and December 6, 2010, Conceptus received at least 16,581 complaints relating to Essure.

299. Of these 16,581 complaints, 16,399 were never reported to the FDA.

300. Conceptus had compiled a spreadsheet of 2,752 complaints about Essure received from July 20, 2010 through December 10, 2010. Not a single one of these that indicated perforation of a patient's organs was reported to the FDA.

301. In fact, during that time period Conceptus reported only 182 complaints total to the FDA.[77]

302. At the close of the inspection on January 6, 2011, the FDA inspector made it abundantly clear to Conceptus officials that an abdominally located coil was the precursor to becoming symptomatic in all cases in which an intra-abdominal coil had to be removed surgically.

303. Nonetheless, Conceptus continued to conceal complaints if a patient had a coil in her peritoneal cavity but was asymptomatic.

[77] *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/results.cfm

304. Conceptus revealed in this inspection that it had no intention of keeping physicians and women fully informed.

305. Conceptus' sole purpose was to maintain the marketability of its device by concealing as much adverse safety information related to its device as it could.

306. Conceptus' fraudulent scheme to conceal reports of device migration and perforation was undertaken in conscious disregard of the health and safety of all Essure patients, and in violation of federal law, the PMA, and parallel state law.

307. Thousands of vulnerable and unsuspecting patients, including the Plaintiffs herein, have been seriously and permanently injured as a result of Conceptus' wrongful, illegal and immoral actions.

iv. Conceptus Demonstrated A Continuing Pattern of Concealing Safety Complaints

308. In 2013, several years after being cited by the FDA for withholding safety information, the FDA discovered again that Conceptus had been concealing thousands of complaints from the agency and the public.

309. Between May and June of 2013, the FDA conducted another inspection of Conceptus' Mountain View, CA facility. This inspection included an evaluation of Conceptus' complaint handling and adverse event reporting practices.

310. The FDA's review revealed 16,047 complaints Conceptus had received regarding Essure between January 2011 and the date of the inspection.

311. Of these 16,047 complaints, Conceptus withheld 15,712 from the FDA, ensuring that they would not be made public.[78]

312. Out of those 16,047, the FDA inspector reviewed 18 random complaints that contained the key words "peritoneal" or "abdominal" with "pain" or pregnancy and discovered that none of the complaints stating that one or more of the coils were imaged outside the fallopian tubes were reported to the FDA if the patient had not reported pain at last contact.

313. Conceptus did not provide an explanation as to why the patient had stopped reporting pain, such as possible removal of the device.

314. Conceptus withheld thousands of complaints of side effects from the FDA for years because it needed to protect the perception that its device was safe.

[78] *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/results.cfm

315. If Essure was ever perceived as unsafe, or not as safe as alternative birth control methods, then the device would not have achieved acceptance in the marketplace and the company would fail.

v. Trends in FDA Reports Prove That Conceptus and Bayer Withheld An Enormous Amount of Safety Information

316. Alarming trends in the FDA's database exist because Conceptus and Bayer chose not to report adverse events to the FDA as required by federal law.

317. The FDA did not receive accurate numbers of safety reports concerning Essure until Conceptus and Bayer no longer controlled the information.

318. The FDA learned of an overwhelming number of Essure adverse events only after women were no longer forced to report their problems directly to Conceptus or Bayer.

319. Between Essure's inception in 2002 and through to 2015, the FDA received approximately 9,900 medical device reports (MDRs) related to safety problems with the device.[79]

320. Of those 9,900 MDRs, only 943 were made between 2002 and October 25, 2013. The FDA received the remaining 8,950 reports between October 26, 2013 and December 31, 2015. [80]

321. Therefore, approximately 90% of all Essure related adverse events were reported after late October of 2013.[81] In other words, the FDA's data shows that 90% of the reported problems with Essure became public in only the most recent 15% of its time on the market.

322. The rate at which women suffered adverse events associated with the Essure device did not change. The device itself did not change. Only the reporting mechanisms changed.

323. Up until late 2013, women adversely affected by Essure had no convenient method of reporting their problems directly to the FDA. These women were thus forced to report their problems solely to Conceptus or Bayer.

324. Around that time, the FDA introduced a new method of reporting adverse events named "MedWatcher."

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[79] *See* http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452254.htm

[80] *See* http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452254.htm

[81] *Id.*

325. MedWatcher is an app that allows individuals to submit their reports of serious medical device problems directly to the FDA through the convenient use of their smart phone or tablet, thus disposing of the need to contact a device manufacturer first.[82]

326. Authors studying Essure adverse event reporting recently concluded that the ability for women to report Essure related complaints via the MedWatcher app resulted in a massive increase in Essure related MDRs reported to the FDA since October 26, 2013.[83]

327. The study, entitled *Increasing Patient Engagement in Pharmacovigilance Through Online Community Outreach and Mobile Reporting Applications: An Analysis of Adverse Event Reporting for the Essure Device in the US*, examined voluntary patient adverse event reporting directly to the FDA using the FDA's new MedWatcher app.[84]

328. The study began by encouraging women in an Essure support group who had been adversely affected by the device to file a report using MedWatcher.[85]

329. The Essure support group was a Facebook group named "Essure Problems" consisting of women who underwent the Essure procedure and began experiencing severe pain and problems related to the device. Currently, the group has over 27,000 members.[86]

330. In October 2013, a representative from the MedWatcher app development team joined the "Essure Problems" group to provide technical support to patients filing adverse event reports via the MedWatcher app.

331. This change in reporting mechanisms directly caused the explosion of adverse event reports that became public after October of 2013.

332. According to "Essure Problems" group administrators, many women with Essure reported these same complaints directly to Conceptus for many years prior to October of 2013.

333. Those women were never contacted for follow-up investigations and Conceptus and Bayer chose not to report the vast majority of those complaints to the FDA.

334. As a result, while Conceptus maintained growing complaint files detailing thousands of problems experienced with the device, the FDA and the public only became aware of a fraction of them.

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[82] *See* http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/ucm385880.htm
[83] *Id.*
[84] *See* "Increasing Patient Engagement in Pharmacovigilance Through Online Community Outreach and Mobile Reporting Applications: An Analysis of Adverse Event Reporting for the Essure Device in the US" available online at: http://link.springer.com/article/10.1007/s40290-015-0106-6/fulltext.html
[85]*See* "Increasing Patient Engagement in Pharmacovigilance Through Online Community Outreach and Mobile Reporting Applications: An Analysis of Adverse Event Reporting for the Essure Device in the US" available online at: http://link.springer.com/article/10.1007/s40290-015-0106-6/fulltext.html
[86] *See* https://www.facebook.com/groups/Essureproblems/

335. Conceptus and Bayer successfully concealed thousands of reports of adverse side effects associated with Essure from the FDA and the public because they controlled the information for years.

vi. Bayer Misled the FDA About Rates of Essure Breaking

336. Despite knowing about hundreds of instances of the Essure device breaking, Bayer has repeatedly reported to the FDA that only single cases exist.

337. Between May 29, 2014 and January 20, 2016, Bayer received at least 462 complaints that a patient's Essure coils had broken apart.

338. When forwarding the first few complaints, Bayer notified the FDA that "single cases have been reported of Essure breakage."

339. However, as reports of breakage continued to mount, Bayer continued to submit to the FDA that only single cases of breakage had been reported.

340. After 100 individual reports of breakage accumulated, Bayer submitted to the FDA that only single cases of breakage had been reported.

341. After 200 individual reports of breakage accumulated, Bayer submitted to the FDA that only single cases of breakage had been reported.

342. After 462 individual reports of breakage accumulated, Bayer submitted to the FDA that only single cases of breakage had been reported.

343. In fact every single report of device fracture or breakage included a statement by Bayer to the FDA stating that "single cases have been reported of Essure breakage."

344. Bayer did this because it knew that the FDA would not discover the trend in the data on its own.

345. Bayer knows that multiple FDA analysts read each individual MDR that it submits, and they do not necessarily communicate with each other or compare data.

346. Therefore, when multiple FDA analysts read separate reports that each state "single cases have been reported of Essure breakage," it causes each individual analyst to falsely believe that instances of device breakage are extremely rare.

347. Bayer's MDRs regarding device breakage were inaccurate, misleading, and not in compliance with MDR reporting requirements.

348. Bayer did this to withhold knowledge from the public and to prevent the FDA from requiring it to make changes to its label concerning device breakage, a condition with potentially life-threatening consequences.

g. NOW THE MEDICAL COMMUNITY IS DISCOVERING WHAT CONCEPTUS AND BAYER KNEW FOR YEARS: ESSURE IS DANGEROUS

i. Women With Essure Are Ten Times More Likely to Undergo Subsequent Surgical Re-Operation Than Women Who Undergo a Tubal Ligation

349. The Essure device leads to far more complications than alternative permanent birth control methods. It is significantly less safe than the traditional alternative method of undergoing a tubal ligation.

350. On October 13, 2015, the British Medical Journal ("BMJ") published a study entitled *Safety and efficacy of hysteroscopic sterilization compared with laparoscopic sterilization: an observational cohort study*, in which Dr. Art Sedrakyan of Weill Cornell Medicine in New York and his colleagues analyzed data from women who had received either the Essure implant or undergone a traditional tubal ligation between 2005 and 2013 in New York State.[87]

351. The data included 8,048 women who underwent the Essure procedure and 44,278 women who had undergone a tubal ligation.

352. This study used data collected from the New York State Department of Health Statewide Planning and Research Cooperative System, which is a database that collects patient and treatment information for every hospital discharge, outpatient service, ambulatory surgery, and emergency department records in New York State.[88]

353. This study is the first large comparative cohort study ever to have been conducted to compare the efficacy and safety of the implant based hysteroscopic procedure with the traditional laparoscopic procedure.[89] It is the largest collection of data related to Essure that was not controlled by Conceptus or Bayer.

354. The study found that women who used Essure as a means for permanent sterilization are ten (10) times more likely to undergo re-operation due to device related complications and injuries compared to women who undergo tubal ligation.[90]

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[87] *See* "Safety and efficacy of hysteroscopic sterilization compared with laparoscopic sterilization: an observational cohort study" available online at: http://www.bmj.com/content/351/bmj.h5162
[88] *Id.*
[89] *Id.*
[90] *Id.*

355. The study reported that although Essure is advertised as a surgery-free alternative to the minimally invasive laparoscopic surgery, women who got Essure often required a major surgery due to complications resulting from Essure, and at far greater rates than the traditional option.[91]

356. The authors also analyzed the Essure MAUDE data and indicated that most of the adverse events reported by patients with Essure were for injuries that would require and did require a subsequent surgical operation.[92] Such injuries included pelvic pain, hemorrhage, and device migration or incompatibility.

357. Reports of chronic pain, hemorrhage, and device migration, which necessitate surgical intervention, are indeed serious injuries and are therefore reportable events.[93]

358. Conceptus and Bayer did not submit any MDR reportable events derived from this study to the FDA.

359. Bayer still falsely claims to this day that Essure is safer than undergoing tubal ligation.

ii. Essure Is Not As Effective As Alternative Methods

360. Women with Essure are more likely to get pregnant than women who undergo a tubal ligation.

361. In March of 2014, the online medical journal Conception published a study entitled *Probability of pregnancy after sterilization: a comparison of hysteroscopic versus laparoscopic sterilization*, which compared the expected probability of pregnancy after hysteroscopic with laparoscopic sterilization based on available data using decision analysis.[94]

362. The study analysis took into account uncertainties in successful placement of coils, return for follow-up confirmation testing and successful blockage of tubes. Using real-life circumstances, the authors concluded that at all points in time after the sterilization procedure, the initial and cumulative risk of pregnancy after sterilization is higher in women who undergo hysteroscopic sterilization than either laparoscopic band or bipolar sterilization.[95]

363. The study found that the expected pregnancy rates per 1000 women at 1 year are 57, 7 and 3 for hysteroscopic sterilization, laparoscopic silicone rubber band application and

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[91] *Id.*
[92] *Id.*
[93] 21 C.F.R. § 803.3 (2012).
[94] *See* "Probability of pregnancy after sterilization: a comparison of hysteroscopic versus laparoscopic sterilization" available at: http://www.contraceptionjournal.org/pb/assets/raw/Health%20Advance/journals/contra/CON-8309-FINAL.pdf
[95] *Id.*

laparoscopic bipolar coagulation, respectively. At 10 years, the cumulative pregnancy rates per 1000 women are 96, 24 and 30, respectively.[96]

364. This means that the probability of getting pregnant at 1 year and over 10 years is higher in women who receive Essure as compared to laparoscopic sterilization.[97]

365. Essure sterilization failure rates after typical use in the community by a variety of physicians on a variety of patients are significantly higher than the failure rates reported to the FDA by the manufacturer in its own highly controlled study.

366. However, Bayer still falsely claims to this day that Essure is more effective than undergoing tubal ligation.

iii. Leading Practitioners Have Criticized Conceptus For Its Lack of Transparency

367. Experts in the field of Gynecology disapprove of Conceptus and Bayer's failure to

368. provide information to the public.

369. On September 23, 2015, the New England Journal of Medicine published an article entitled *Revisiting Essure – Toward Safe and Effective Sterilization*. Authored by several prominent gynecologists, the article expressed concerns about the inadequacy of Essure's premarketing and postmarketing studies.[98]

370. More specifically, the authors identified problems relative to incomplete follow-up with patients and biased results.

371. Ultimately, the authors concluded that many of the Essure adverse events and safety concerns, along with problems with the device's effectiveness, might have been detected sooner or avoided altogether if there had been higher-quality premarketing and postmarketing evaluations and more timely and transparent dissemination of study results by the manufacturers.[99]

372. Coinciding with other developing understandings, the article notes that evidence suggests that Essure is neither as effective nor as safe as the premarketing-approval evaluation indicated.[100]

h. THE REVELATION OF SAFETY INFORMATION IN THE PUBLIC LEADS TO THE INEVITABLE: FDA MANDATES MAJOR CHANGES TO ESSURE SALES

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[96] *Id.*
[97] *Id.*
[98] *See* "Revisiting Essure – Toward Safe and Effective Sterilization" available online at: http://www.nejm.org/doi/full/10.1056/NEJMp1510514
[99] *Id.*
[100] *Id.*

373. As thousands of reports about Essure's true safety risks became public recently, the FDA fixed the glaring problem by forcing drastic changes to the product's warning label and taking extreme measures to ensure that patients are fully informed of the risks.

374. Patients and physicians have reported to the FDA upwards of 9,000 adverse events related to Essure since October 2013. This significant increase prompted the FDA to convene a meeting of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee to examine safety concerns about Essure raised by patients and cited in MDRs.

375. The meeting was held on September 24, 2015 and FDA heard available scientific data pertaining to Essure's safety and effectiveness, expert scientific and clinical opinions on the risks and benefits of Essure, and concerns and experiences of women implanted with the device.

376. On February 29, 2016 the FDA announced that it will force a major change to the Essure warning label and also require all women considering receiving Essure to fill out a "Patient Decision Checklist" to ensure that they are fully informed of the true risks.[101]

377. The FDA stated that such warnings are needed for a woman to understand the risks as compared to alternative options and then decide whether the product is right for her.[102]

378. The new warning and checklist will change the risk/benefit profile of Essure for all potential patients. It will reveal the alternatives as far better choices for many women. It will lead to far less patients choosing to use the Essure system.

379. This result is why Conceptus and Bayer withheld safety information from the FDA and the public for years.

380. Conceptus and Bayer knew that if the true risks of Essure were known to the FDA, then they would inevitably be communicated to physicians and women.

381. Conceptus and Bayer knew that if physicians and women understood the true risks of Essure, then sales of the device would be devastated.

382. Conceptus and Bayer withheld thousands of complaints of side effects from the FDA for years to protect and promote the false perception that the Essure device was safe.

383. If Essure was ever perceived as unsafe, or not as safe as alternative birth control methods, then the device would not have achieved market acceptance and the company would fail.

[101] *See* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm488313.htm
[102] *Id.*

384. To protect sales and revenue, Conceptus and Bayer purposefully ignored their mandatory federal reporting requirements and actively hid safety information from the public for as long as they could.

i. FDA Orders Bayer to Give Warnings Indicating The Highest Level of Risk

385. In February of 2016, the FDA determined that a boxed warning needed to be a part of the Essure warning label.

386. FDA reserves boxed warnings for only the most serious adverse events, and they indicate the highest level of risk.

387. As of November of 2016, the Essure warning label now contains the following "black box warning":

> **WARNING: Some patients implanted with the Essure System for Permanent Birth Control have experienced and/or reported adverse events, including perforation of the uterus and/or fallopian tubes, identification of inserts in the abdominal or pelvic cavity, persistent pain, and suspected allergic or hypersensitivity reactions. If the device needs to be removed to address such an adverse event, a surgical procedure will be required. This information should be shared with patients considering sterilization with the Essure System of Permanent Birth Control during discussion of the benefits and risks of the device.**[103]

388. This boxed warning directly addresses side effects that Conceptus and Bayer had been cited for hiding from the FDA and the public for years.

389. The advent of this warning illustrates the significance of Conceptus and Bayer's illegal and immoral behavior.

390. Conceptus and Bayer hid safety information about the most serious adverse events and the highest levels of risk from patients.

391. If Conceptus and Bayer had not broken the law by violating federal reporting violations, the public would have known about these safety risks years earlier.

392. Thousands of women who decided to receive the Essure device would have received the knowledge that they deserved, and thousands of injuries could have been prevented.

393. Conceptus and Bayer could have prevented this problem by updating their warnings to patients.

394. Conceptus and Bayer did all in their power to keep serious side effects and warnings off of the Essure label for years.

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[103] *See* "Patient Information Booklet," available online at: http://labeling.bayerhealthcare.com/html/products/pi/essure_pib_en.pdf.

395. Over the course of many years, despite knowing of hundreds of instances where the Essure device had migrated from its proper position, Conceptus did not warn of this potential problem.

396. After being caught by the FDA in 2011 for not reporting migration events, the company still refused to warn about this problem on its label.

397. It was not until 2013 that Conceptus even acknowledged migration events on the Essure label.

398. At that time, Conceptus changed the warning label to state only that "There are reports of the Essure insert migrating."

399. This warning gravely downplayed the true incidence of risk that a woman's Essure coils might migrate.

400. Conceptus should have been adequately informing women about migrations.

401. This issue illustrates Conceptus' policy of deliberately refusing to provide adequate warnings to physicians and patients.

402. For years Conceptus and Bayer have downplayed on the Essure warning label the true risks of migration, as well as perforation, persistent pain, allergy or hypersensitivity reactions, the likelihood of reoperation, and other serious side effects.

403. The FDA has now forced what could and should have been done years ago.

ii. FDA Takes Drastic Measures to Ensure Patients Are Fully Informed

404. Because Conceptus and Bayer denied thousands of women the information that they deserved, the FDA now mandates that every potential Essure patient receive and sign a detailed patient-decision checklist.

405. This patient-decision checklist requires that the patient and physician each sign the checklist, acknowledging that the risks associated with Essure have been disclosed and explained.

406. The checklist specifically warns of device migration and perforation of organs, side effects that Conceptus and Bayer had been cited for hiding from the FDA and the public for years.

407. Most importantly, the checklist describes the review of its form as a critical step in deciding whether to have the Essure device implanted, and suggests that a woman should carefully consider the risks before making the decision.

408. The checklist enhances the warnings given to potential Essure patients and completely alters the process of undergoing the procedure.

409. The checklist has a major impact on the risk/benefit profile of the device, and will inevitably lead to less patients choosing Essure. It will have a major negative impact on Essure sales.

i. FACED WITH MOUNTING SIDE EFFECTS, CONGRESS IS WORKING TOWARD BANNING SALES OF ESSURE

410. As the public has become more informed about the true safety risks associated with Essure, Congress has moved toward banning its sale completely.

411. Pennsylvania Congressman Mike Fitzpatrick has been the leading voice in Congress calling for removal of Essure from the market.

412. On November 4, 2015, Congressman Fitzpatrick introduced a bipartisan bill entitled the "E-Free Act" with the goal of taking Essure off the market.

413. Congressman Fitzpatrick stated that it was imperative that Bayer immediately end production of a product that poses such a danger to patient safety.

414. A consulting firm specializing in medical device postmarketing surveillance, Device Events, recently analyzed data provided to the FDA for the Congressman. The analysis uncovered raw data showing a total of 303 fetal deaths among women who had the Essure device and revealed discrepancies in Conceptus and Bayer's reporting practices. Previously, the agency had believed that there were only five such cases.

415. The analysis showed that the manufacturer's reports are falsely marked as mere injury or malfunction reports. However, they describe instances of miscarriage, abortion or fetal death, and should have been categorized as "death" reports.

416. Congressman Fitzpatrick subsequently wrote directly to the Center for Devices and Radiological Health at FDA and urged them to immediately consider the data due to its grave nature.

j. CONCEPTUS AND BAYER'S PARTICIPATION IN THE COVERING UP OF AND FAILURE TO ADEQUATELY WARN OF SERIOUS ADVERSE EVENTS AND INCREASED RISKS AND COMPLICATIONS ASSOCIATED WITH ESSURE CAUSED PLAINTIFFS' INJURIES

417. A manufacturer has the duty to provide adequate and timely warnings regarding increased risks and dangers associated with the foreseeable uses of its product.

418. Conceptus and Bayer grossly failed to satisfy their duties mandated by federal law, the Essure PMA, and state common law duties.

419. Conceptus and Bayer did not provide adequate and timely warnings or instructions regarding the true risks of Essure.

420. Conceptus and Bayer disseminated misleading and false information concerning the true risks of Essure.

421. Conceptus and Bayer purposefully concealed the serious increased risks and complications associated with Essure.

422. Conceptus and Bayer failed to take the required actions when they learned that Essure was causing thousands of problems in patients.

423. Bayer cannot and should not be permitted to absolve itself from liability by pointing to the FDCA or the MDA, claiming preemption, when it was Conceptus and Bayer who chose to violate the law and deliberately conceal their knowledge of the increased risks, complications, and the serious and dangerous adverse side effects associated with Essure.

424. Bayer cannot and should not be permitted to absolve itself from liability when it was Conceptus and Bayer who, in violation of federal law and the PMA, concealed and failed to report the true number of adverse events being reported by women with Essure.

425. A medical device manufacturer only receives the benefits afforded by federal law, i.e. the FDCA and MDA, when it abides by federal law.

426. Federal law requires that a manufacturer report all known adverse events associated with a medical device to the FDA.

427. Not only did Conceptus and Bayer not provide the Plaintiffs' physician nor Plaintiffs with the necessary information in order to make an informed decision in the best interests of Plaintiffs' health, but they purposefully deceived Plaintiffs' physicians and the Plaintiffs as to the safety and efficacy of Essure.

428. Conceptus and Bayer did not discharge their duty, required by federal law, the Essure PMA, and state common law duties to adequately and fully warn and inform Plaintiffs' physcians and Plaintiffs of the known dangers and increased risks associated with the use of Essure.

429. Plaintiffs' physician and Plaintiffs reasonably relied, and did rely, on Conceptus and Bayer's misrepresentations and concealments.

430. Moreover, Plaintiffs would not have consented to undergo the Essure procedure had they been fully informed of its increased dangers, risks, and adverse consequences.

431. As a direct and proximate result of Conceptus and Bayer's fraudulent concealment and misrepresentations concerning material health and safety risks associated with Essure, Plaintiffs were permanently injured and suffered and will continue to suffer injuries, damages, and economic loss.

432. As a direct and proximate result of Conceptus and Bayer's fraudulent concealment and misrepresentations concerning material health and safety risks associated with Essure, Plaintiffs have been injured and incurred damages, including but not limited to medical and hospital expenses, physical and mental pain and suffering, and loss of the quality and enjoyment of life as a result.

V. EQUITABLE TOLLING/FRAUDULENT CONCEALMENT

433. Plaintiffs repeat and incorporate by reference all other paragraphs of this Petition as if fully set forth herein and further alleges as follows:

434. Conceptus and Bayer's failure to report, document, or follow up on the known adverse event complaints, and concealment of adverse events, known defects, serious increased risks, dangers, and complications, constitutes fraudulent concealment that equitably tolls any proffered statute of limitation that may otherwise bar the recovery sought by Plaintiffs herein.

435. Bayer is estopped from relying on any statute of limitations defense because it continued to refute and deny reports and studies questioning the safety of Essure, actively and intentionally concealed the defects, suppressed reports and adverse information, sponsored and paid for studies which falsely characterized the risks and benefits of Essure, failed to satisfy FDA and PMA requirements, failed to satisfy FDA and PMA notification requirements, and failed to disclose known dangerous defects and serious increased risks and complications to physicians and the Plaintiffs.

436. Instead, Conceptus and Bayer continued/continues to represent that Essure was/is safer, more effective and the best alternative for permanent female sterilization all the while they knew that this was absolutely false and not true, even after the recent Cornell study was published and patient complaints accumulated in the thousands.

437. Conceptus and Bayer did the above acts which were and are illegal under federal law, the PMA and parallel state law, to effectively market Essure and encourage physicians, including Plaintiffs' physicians, to recommend and perform the Essure procedure.

438. Conceptus and Bayer did the above acts which were and are illegal under federal law, the PMA and parallel state law, to encourage patients, including Plaintiffs, to undergo the Essure procedure rather than choose an alternative procedure, such as a traditional tubal ligation.

439. At all relevant times, Conceptus and Bayer were under a continuing duty under federal law, the PMA and parallel state laws to disclose the true character, quality, and nature of the increased risks, adverse events, and dangers associated with Essure.

440. As a result of Conceptus and Bayer's concealment of the true character, quality and nature of their product, they are estopped from relying on any statute of limitations defense.

441. Conceptus and Bayer furthered their fraudulent concealment through act and omission, including misrepresenting known dangers and/or defects in Essure and/or arising out of the use of Essure and a continued and systematic failure to disclose and/or cover-up such information from/to the Plaintiffs, Plaintiffs' physicians, and the public.

442. Conceptus and Bayer's acts and omissions, before, during and/or after the act causing Plaintiffs' injury, prevented Plaintiffs and/or Plaintiffs physicians from discovering the injury or cause thereof until recently.

443. Conceptus and Bayer's conduct, because it was purposely committed, was known or should have been known by them to be dangerous, heedless, reckless, and without regard to the consequences or the rights and safety of the Plaintiffs.

VI. GENERAL ALLEGATIONS

444. Plaintiffs repeat and incorporate by reference all other paragraphs of this Petition as if fully set forth herein and further allege as follows:

445. At all relevant times, Essure was researched, developed, manufactured, marketed, promoted, advertised, sold and distributed by Conceptus and Bayer.

446. Conceptus and Bayer negligently, carelessly, and/or recklessly manufactured, marketed, advertised, promoted, sold and distributed Essure as a safe and effective device to be used for permanent female sterilization.

447. Conceptus and Bayer knew, and/or had reason to know, that Essure was defective, unreasonably dangerous and not safe because of the thousands of adverse events that both companies knew about.

Representations

448. Conceptus and Bayer negligently, carelessly, recklessly, and/or intentionally promoted Essure to physicians and patients, including the Plaintiffs and Plaintiffs' physicians.

449. Conceptus and Bayer downplayed to physicians and patients, including Plaintiffs and Plaintiffs' physicians, the dangerous side effects of Essure.

450. Conceptus and Bayer misrepresented the safety of Essure to physicians and patients, including Plaintiffs and Plaintiffs' physicians.

451. Conceptus and Bayer willfully and/or intentionally failed to warn and/or alert physicians and patients, including Plaintiffs and Plaintiffs' physicians, of the increased risks and significant dangers resulting from being implanted with the Essure device.

452. Conceptus and Bayer knew and/or had reason to know, that their representations and suggestions to physicians that Essure was safe and more effective than alternative permanent sterilization methods were materially false and misleading such that physicians and patients, including Plaintiffs and Plaintiffs' physicians, would rely on such representations.

453. Conceptus and Bayer knew or should have known and/or recklessly disregarded the materially incomplete, false, and misleading nature of the information that they caused to be disseminated to the public and to physicians, including Plaintiffs and Plaintiffs' physicians, as part of their surreptitious campaign to promote Essure.

454. Any warnings Conceptus and Bayer may have issued concerning the risks and dangers of Essure were inadequate and insufficient in light of their contradictory prior, contemporaneous and continuing illegal promotional efforts of Essure to hide or downplay the true risks and serious dangers of the device.

455. The ongoing scheme described herein could not have been perpetrated over a substantial period of time, as has occurred here, without knowledge and complicity of personnel at the highest levels of Conceptus and Bayer, including the corporate officers and directors.

456. Conceptus and Bayer knew and/or had reason to know of the likelihood of serious injuries caused by the promotion, sale, and distribution of Essure, but they concealed this information and did not warn the FDA, Plaintiff or Plaintiffs' physicians, preventing Plaintiff and Plaintiffs' physicians from making informed choices in selecting alternative sterilization procedures prior to Plaintiffs' Essure implantation procedure and preventing Plaintiff and Plaintiffs' physicians from timely discovering Plaintiffs' injuries.

Causation

457. Plaintiffs would not have consented to undergo the Essure procedure had Plaintiffs known of or been fully and adequately informed by Conceptus and Bayer of the true increased risks, hazards, and serious dangers of Essure.

458. Plaintiffs and Plaintiffs' physicians reasonably relied on Defendants' representations and omissions regarding the safety and efficacy of Essure.

459. Plaintiffs and Plaintiffs' physicians did not know of the specific increased risks and serious dangers, and/or were misled by Conceptus and Bayer, who knew or should have known of the true risks and dangers, but consciously chose not to inform Plaintiffs or their physicians of those risks and to actively misrepresent those risks and dangers to the Plaintiffs and Plaintiffs' physicians. Conceptus and Bayer's promotion and marketing of Essure caused Plaintiffs' physicians to decide to recommend and implant Essure in Plaintiffs. Plaintiffs' physicians would not have recommended and performed the Essure procedure in the absence of Conceptus and Bayer's false and misleading promotion.

Damages

460. Plaintiffs have suffered serious personal injuries as a direct and proximate result of Conceptus and Bayer's illegal misconduct.

461. As a direct and proximate result of Conceptus and Bayer's illegal conduct, Plaintiffs have suffered and will continue to suffer from severe injuries and damages, including but not limited to irregular heavy menstrual cycle bleeding, organ perforation, and severe chronic pain which required surgical intervention to remove the Essure coils or will require surgical intervention to remove the Essure coils in the future.

462. As a result of Conceptus and Bayer's failure to warn of the risks, dangers, and adverse events associated with Essure as manufactured, promoted, sold and supplied by both companies, and as a result of the negligence, callousness, and other wrongdoing and misconduct of Conceptus and Bayer as described herein:

A) Plaintiffs have been injured and suffered and will continue to suffer injuries to their body and mind, the exact nature of which are not completely known to date;

B) Plaintiffs have sustained and will continue to sustain economic losses, including loss of earnings and diminution of the loss of earning capacity, the exact amount of which is presently unknown;

C) Plaintiffs have incurred and will be required to incur additional medical expenses in the future to care for themselves as a result of the injuries and damages Plaintiffs have suffered;

D) Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interests thereon and costs.

463. Plaintiffs had no reason until recently to suspect that their chronic pain and injuries were caused by Essure. Thus, Plaintiffs did not know and could not have known and through the exercise of reasonable diligence, that the Essure device caused their injuries.

464. Each of the Plaintiffs herein brings their respective actions within the applicable statutes of limitations. Specifically, Plaintiffs bring their actions within the prescribed time limits following their injuries and their knowledge of the wrongful cause. Prior to such time, Plaintiffs did not know nor have reason to know of their injuries and/or the wrongful cause thereof.

465. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

VI. SPECIFIC PLAINTIFF ALLEGATIONS

466. Plaintiffs repeat and incorporate by reference all other paragraphs of this Petition as if fully set forth herein and further allege as follows:

1. Laveta Jordan

467. Plaintiff Laveta Jordan is a resident of St. Louis, Missouri. Plaintiff was born on June 26, 1981. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

468. On or around February 28, 2014, Plaintiff underwent the Essure procedure at the Barnes Jewish Hospital in St. Louis, Missouri.

Post Essure Procedure Condition and Treatment:

469. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including chronic pelvic pain, chronic back pain, abdominal pain, pain during intercourse, excessive dental problems, depression, and excessive rashes. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

470. Plaintiff subsequently sought treatment for her symptoms at the Barnes Jewish Hospital in St. Louis, Missouri, and from her physicians in St. Louis, Missouri, but was unable to resolve her symptoms.

471. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

2. Heather Henk

472. Plaintiff Heather Henk is a resident of Covington, Indiana. Plaintiff was born on January 15, 1983. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

473. On or around July 25, 2013, Plaintiff underwent the Essure procedure in Champaign, Illinois.

Post Essure Procedure Condition and Treatment:

474. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, excessive hair loss, and chronic pelvic pain. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

475. Plaintiff subsequently sought treatment for her symptoms from her physician in Champaign Illinois, but has been unable to resolve her symptoms.

476. Plaintiff's treating physician informed Plaintiff that her left Essure coil and fallopian tube would need to be removed in order for her pains to be resolved.

477. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

3. Janna Laatu

478. Plaintiff Janna Laatu is a resident of Belle Vernon, Pennsylvania. Plaintiff was born on December 16, 1984. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

479. On or around February 10, 2012, Plaintiff underwent the Essure procedure in Uniontown, Pennsylvania.

Post Essure Procedure Condition and Treatment:

480. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic back pain, and abdominal pain. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

481. Plaintiff subsequently sought treatment for her symptoms from her physician in Monongahela, Pennsylvania, but was unable to resolve her symptoms.

482. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

4. Tymesha Hunt

483. Plaintiff Tymesha Hunt is a resident of Bridgeville, Delaware. Plaintiff was born on February 10, 1984. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

484. On or around May 3, 2011, Plaintiff underwent the Essure procedure in Seaford, Delaware.

Post Essure Procedure Condition and Treatment:

485. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, chronic back pain, abdominal pain, excessive hair loss, seizures and excessive migraine headaches. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

486. Plaintiff subsequently sought treatment for her symptoms from her physicians in Staten Island, New York, but was unable to resolve her symptoms.

487. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

5. Jennifer Baggett

488. Plaintiff Jennifer Baggett is a resident of High Ridge, Missouri. Plaintiff was born on April 22, 1985. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

489. On or around July 7, 2009, Plaintiff underwent the Essure procedure in St. Louis, Missouri.

Post Essure Procedure Condition and Treatment:

490. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including painful menstrual bleeding, heavy menstrual bleeding, chronic pelvic pain, abdominal bloating, excessive weight gain, and abdominal pain. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

491. Plaintiff subsequently sought treatment for her symptoms from her physicians in St. Louis, Missouri, but was unable to resolve her symptoms.

492. In or around September of 2014, Plaintiff underwent surgery to remove her Essure coils at the Mercy Hospital in St. Louis, Missouri.

493. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

6. Ashley Baird

494. Plaintiff Ashley Baird is a resident of Andrews, Texas. Plaintiff was born on April 21, 1988. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

495. On or around October 30 2012, Plaintiff underwent the Essure procedure in Odessa, Texas.

Post Essure Procedure Condition and Treatment:

496. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including chronic back pain, abdominal pain, severe headaches, persistent lethargy, nausea, and chronic fatigue. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

497. Plaintiff subsequently sought treatment for her symptoms from her physicians in Odessa, Texas and Andrews, Texas, but was unable to resolve her symptoms.

498. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

7. Jessica Blair

499. Plaintiff Jessica Blair is a resident of Mount Vernon, Ohio. Plaintiff was born on October 7, 1980. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

500. In or around September of 2009, Plaintiff underwent the Essure procedure in Columbus, Ohio.

Post Essure Procedure Condition and Treatment:

501. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, chronic back pain, abdominal pain, excessive hair loss, vitamin D deficiency, and a fibromyalgia diagnosis. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

502. Plaintiff subsequently sought treatment for her symptoms from her physicians in Westerville, Ohio, but was unable to resolve her symptoms.

503. On or around May 27, 2016, Plaintiff underwent surgery to remove her Essure coils at Mount Carmel St. Ann Hospital in Westerville, Ohio.

504. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

8. Meagan Brady

505. Plaintiff Meagan Brady is a resident of Casa Grande, Arizona. Plaintiff was born on July 8, 1984. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

506. On or around February 15, 2011, Plaintiff underwent the Essure procedure in Mesa, Arizona.

Post Essure Procedure Condition and Treatment:

507. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including excessive hair loss, pain during intercourse, excessive abdominal bloating, excessive weight gain, excessive dental problems, and excessive rashes. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

508. Plaintiff subsequently sought treatment for her symptoms from her physician in Mesa, Arizona, but was unable to resolve her symptoms.

509. On or around January 19, 2015, Plaintiff underwent a hysterectomy to remove her Essure coils at Banner Baywood Medical Center in Mesa, Arizona.

510. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

9. Darla Brown

511. Plaintiff Darla Brown is a resident of Woodward, Oklahoma. Plaintiff was born on February 16, 1982. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

512. In or around 2009, Plaintiff underwent the Essure procedure in Fort Hood, Texas.

Post Essure Procedure Condition and Treatment:

513. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, abdominal pain, chronic pelvic pain, chronic back pain, and hair loss. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

514. Plaintiff subsequently sought treatment for her symptoms from her physicians, but was unable to resolve her symptoms.

515. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

10. Christine Clark

516. Plaintiff Christine Clark is a resident of Ratcliff, Arkansas. Plaintiff was born on December 29, 1987. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

517. In or around September of 2010, Plaintiff underwent the Essure procedure in Forrest City, Arkansas.

Post Essure Procedure Condition and Treatment:

518. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, abdominal pain, chronic pelvic pain, chronic back pain, excessive headaches, depression, chronic fatigue, excessive weight gain, and anxiety. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

519. Plaintiff subsequently sought treatment for her symptoms from her physicians in Ratcliff, Arkansas, Clarksville, Arkansas, and Clarendon, Arkansas, but was unable to resolve her symptoms.

520. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

11. Christine Clark

521. Plaintiff Christine Clark is a resident of Vancouver, Washington. Plaintiff was born on July 11, 1971. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

522. On or around February 25, 2009, Plaintiff underwent the Essure procedure in Vancouver, Washington.

Post Essure Procedure Condition and Treatment:

523. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, chronic back pain, abdominal pain, and ovarian cysts. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

524. Plaintiff subsequently sought treatment for her symptoms from her physicians in Vancouver, Washington but was unable to resolve her symptoms.

525. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

12. Ajike Coates

526. Plaintiff Ajike Coates is a resident of Wetumpka, Alabama. Plaintiff was born on August 19, 1989. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

527. In or around November of 2011, Plaintiff underwent the Essure procedure in Pascagoula, Mississippi.

Post Essure Procedure Condition and Treatment:

528. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, chronic back pain, abdominal pain, pain during intercourse, abdominal bloating, ovarian cysts, and excessive hair loss. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

529. Plaintiff subsequently sought treatment for her symptoms at Springhill Hospital in Mobile, Alabama; DCH Regional Medical Center in Tuscaloosa, Alabama; Singing River Hospital in Pascagoula, Mississippi; and from her physicians in Mobile, Alabama and Grove Hill, Alabama, but was unable to resolve her symptoms.

530. In or around March 2015 Plaintiff underwent surgery to remove her Essure coils at USA Children's & Women's Hospital in Mobile, Alabama.

531. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

13. Ebony Cox

532. Plaintiff Ebony Cox is a resident of Harriet, Arkansas. Plaintiff was born on March 24, 1983. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

533. In or around December of 2006, Plaintiff underwent the Essure procedure in Mountain Helm, Arkansas.

Post Essure Procedure Condition and Treatment:

534. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, chronic back pain, excessive hair loss, chronic fatigue, abdominal pain, pain during intercourse, and dental problems. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

535. Plaintiff subsequently sought treatment for her symptoms from her physician in Little Rock, Arkansas, but was unable to resolve her symptoms.

536. On or around September 8, 2016, Plaintiff underwent surgery to remove her Essure coils at Baptist Medical in Little Rock, Arkansas.

537. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

14. Cheryl Denbow

538. Plaintiff Cheryl Denbow is a resident of Cedar Hill, Missouri. Plaintiff was born on July 31, 1981. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

539. On or around August 18, 2008, Plaintiff underwent the Essure procedure in St. Louis, Missouri.

Post Essure Procedure Condition and Treatment:

540. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, abdominal pain, chronic pelvic pain, and pain during intercourse. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

541. Plaintiff subsequently sought treatment for her symptoms from her physicians in St. Louis, Missouri, but was unable to resolve her symptoms.

542. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

15. Dawn Diaz

543. Plaintiff Dawn Diaz is a resident of Denver, Colorado. Plaintiff was born on November 16, 1981. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

544. In or around December of 2014, Plaintiff underwent the Essure procedure in Denver, Colorado.

Post Essure Procedure Condition and Treatment:

545. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, chronic back pain, abdominal pain, excessive weight gain, excessive rashes, pain during intercourse, excessive hair loss, and excessive migraine headaches. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

546. Plaintiff subsequently sought treatment for her symptoms from her physicians in Denver, Colorado, but was unable to resolve her symptoms.

547. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

16. Dezire Diaz

548. Plaintiff Dezire Diaz is a resident of Colorado Springs, Colorado. Plaintiff was born on May 9, 1990. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

549. In or around October of 2015, Plaintiff underwent the Essure procedure in Colorado Springs, Colorado.

Post Essure Procedure Condition and Treatment:

550. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including chronic pelvic pain, chronic back pain, abdominal pain, excessive hair loss, pain during intercourse, and excessive rashes. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

551. Plaintiff subsequently sought treatment for her symptoms from her physician in Colorado Springs, Colorado, but was unable to resolve her symptoms.

552. On or around August 30, 2016, Plaintiff underwent surgery to remove her Essure coils at Penrose St. Francis North Hospital in Colorado Springs, Colorado.

553. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

17. Jennifer Dischbein

554. Plaintiff Jennifer Dischbein is a resident of Pontoon Beach, Illinois. Plaintiff was born on September 15, 1974. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

555. In or around April of 2009, Plaintiff underwent the Essure procedure in St. Louis, Missouri.

Post Essure Procedure Condition and Treatment:

556. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding,

chronic pelvic pain, excessive weight gain, depression, anxiety, and abdominal pain. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

557. Plaintiff subsequently sought treatment for her symptoms from her physician in St. Louis, Missouri, but was unable to resolve her symptoms.

558. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

18. Arlene Dominguez

559. Plaintiff Arlene Dominguez is a resident of El Paso, Texas. Plaintiff was born on April 25, 1978. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

560. On or around February 25, 2008, Plaintiff underwent the Essure procedure in El Paso, Texas.

Post Essure Procedure Condition and Treatment:

561. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including chronic pelvic pain, chronic back pain, excessive hair loss, abdominal pain, memory loss, depression, anxiety, dizziness, migraine headaches, and chronic fatigue. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

562. Plaintiff subsequently sought treatment for her symptoms at the University Medical Center in El Paso, Texas, and from her physician in El Paso, Texas, but was unable to resolve her symptoms.

563. On or around February 2, 2016, Plaintiff underwent surgery to remove her Essure coils at The Hospitals of Providence - Sierra Campus in El Paso, Texas.

564. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

19. Natasha Ebarb

565. Plaintiff Natasha Ebarb is a resident of Rossville, Georgia. Plaintiff was born on March 11, 1982. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

566. On or around May 24, 2010, Plaintiff underwent the Essure procedure in Galveston, Texas.

Post Essure Procedure Condition and Treatment:

567. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, chronic back pain, abdominal pain, pain during intercourse, hair loss, dental problems, and excessive migraine headaches. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

568. Plaintiff subsequently sought treatment for her symptoms from her physicians in Galveston, Texas and Chattanooga, Tennessee, but was unable to resolve her symptoms.

569. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

20. Noelle Edwards

570. Plaintiff Noelle Edwards is a resident of Liberty Township, Ohio. Plaintiff was born on November 6, 1979. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

571. In or around July 2015, Plaintiff underwent the Essure procedure in Mason, Ohio.

Post Essure Procedure Condition and Treatment:

572. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic back pain, chronic pelvic pain, abdominal pain, pain during intercourse, abdominal bloating, excessive rashes, excessive weight gain, and frequent bacterial infections. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

573. Plaintiff subsequently sought treatment for her symptoms at UC Health West Chester Hospital in West Chester Township, Ohio; Bethesda North Hospital in Cincinnati, Ohio; and from her physicians in Mason, Ohio; Westchester, Ohio; and Cincinnati, Ohio, but was unable to resolve her symptoms.

574. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

21. Stacey Euells

575. Plaintiff Stacy Euells is a resident of Powder Springs, Georgia. Plaintiff was born on January 30, 1987. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

576. In or around September of 2011, Plaintiff underwent the Essure procedure in Decatur, Georgia.

Post Essure Procedure Condition and Treatment:

577. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic back pain, chronic pelvic pain, dental issues, abdominal bloating, pain during intercourse, excessive hair loss, abdominal bloating, and abdominal pain. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

578. Plaintiff subsequently sought treatment for her symptoms at the WellStar Kennestone Regional Medical Center in Marietta, Georgia, but was unable to resolve her symptoms.

579. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

22. Renee Ewing

580. Plaintiff Renee Ewing is a resident of Genoa, Colorado. Plaintiff was born on January 29, 1978. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

581. In or around 2008, Plaintiff underwent the Essure procedure in Colorado Springs, Colorado.

Post Essure Procedure Condition and Treatment:

582. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, chronic back pain, abdominal pain, chronic fatigue, pain during intercourse, and excessive weight gain. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

583. Plaintiff subsequently sought treatment for her symptoms from her physician in Hugo, Colorado, but was unable to resolve her symptoms.

584. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

23. Shaleena Fonua

585. Plaintiff Shaleena Fonua is a resident of Roy, Utah. Plaintiff was born on October 15, 1986. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

586. In or around November of 2011, Plaintiff underwent the Essure procedure in Orem, Utah.

Post Essure Procedure Condition and Treatment:

587. After undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic back pain, chronic pelvic pain, pain during intercourse, depression, chronic fatigue, abdominal bloating, excessive weight gain, excessive rashes, dental problems, and abdominal pain. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

588. Plaintiff subsequently sought treatment for her symptoms from her physician in Salt Lake City, Utah, but was unable to resolve her symptoms.

589. On or around February 5, 2015, Plaintiff underwent surgery to remove her Essure coils at the University of Utah Hospital in Salt Lake City, Utah.

590. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

24. Eugenia Gall

591. Plaintiff Eugenia Gall is a resident of Paragould, Arkansas. Plaintiff was born on November 23, 1976. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

592. In or around May of 2015, Plaintiff underwent the Essure procedure in Jonesboro, Arkansas. However, her physician was only able to place one Essure coil in one fallopian tube.

Post Essure Procedure Condition and Treatment:

593. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed, but that one fallopian tube remained patent. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, chronic back pain, abdominal bloating,

and abdominal pain. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

594. Plaintiff subsequently sought treatment for her symptoms from her physicians in Jonesboro, Arkansas, but was unable to resolve her symptoms.

595. In or around November of 2015, Plaintiff underwent surgery to remove her Essure coil at NEA Baptist Memorial Hospital in Jonesboro, Arkansas.

596. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

25. Nicole Garza

597. Plaintiff Nicole Garza is a resident of Mount Enterprise, Texas. Plaintiff was born on April 22, 1992. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

598. On or around October 10, 2013, Plaintiff underwent the Essure procedure in Nacogdoches, Texas.

Post Essure Procedure Condition and Treatment:

599. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, chronic back pain, abdominal pain, pain during intercourse, excessive weight gain, frequent infections, abdominal bloating, migraine headaches, and excessive hair loss. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

600. Plaintiff subsequently sought treatment for her symptoms at Hospitals in Henderson, Texas; Tyler, Texas; and Center City, Texas, but was unable to resolve her symptoms.

601. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

26. Iliana Gonzalez

602. Plaintiff Iliana Gonzalez is a resident of Bronx, New York. Plaintiff was born on November 2, 1983. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

603. In or around January of 2015, Plaintiff underwent the Essure procedure in New York, New York.

Post Essure Procedure Condition and Treatment:

604. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe chronic pelvic pain. Plaintiff never experienced this condition prior to undergoing the Essure procedure.

605. Plaintiff subsequently sought treatment for her symptoms from her physicians in New York, New York, but was unable to resolve her symptoms.

606. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

27. Teresa Graham

607. Plaintiff Teresa Graham is a resident of Lancaster, California. Plaintiff was born on October 25, 1981. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

608. In or around August 2015, Plaintiff underwent the Essure procedure in Mission Hills, California.

Post Essure Procedure Condition and Treatment:

609. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her Essure coils could not be visualized in her fallopian tube.

610. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including chronic pelvic pain, chronic back pain, and abdominal pain. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

611. Plaintiff subsequently sought treatment for her symptoms at the Valley Presbyterian Hospital in Van Nuys, California, and from her physician in Mission Hills, California, but was unable to resolve her symptoms.

612. In or around November of 2015, Plaintiff underwent surgery to remove her Essure coils at the Valley Presbyterian Hospital in Van Nuys, California.

613. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

28. Candace Grof

614. Plaintiff Candace Grof is a resident of Henderson, Nevada. Plaintiff was born on March 23, 1981. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

615. In or around March 2010, Plaintiff underwent the Essure procedure in Ventura, California.

Post Essure Procedure Condition and Treatment:

616. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that one coil had migrated out of her fallopian tube, and the second fallopian tube was patent.

617. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, chronic back pain, pain during intercourse, excessive hair loss, and abdominal pain. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

618. Plaintiff subsequently sought treatment for her symptoms at an urgent care facility in Henderson, Nevada, and from her physicians in Ventura, California, but was unable to resolve her symptoms.

619. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

29. Amy Head

620. Plaintiff Amy Head is a resident of Fort Smith, Arkansas. Plaintiff was born on January 28, 1978. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

621. In or around March of 2011, Plaintiff underwent the Essure procedure in Fort Smith, Arkansas.

Post Essure Procedure Condition and Treatment:

622. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, chronic back pain, abdominal pain, excessive hair loss, excessive dental problems, excessive rashes, and pain during intercourse. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

623. Plaintiff subsequently sought treatment for her symptoms from her physician in Fort Smith, Arkansas, but was unable to resolve her symptoms.

624. In or around June of 2016, Plaintiff underwent surgery to remove her Essure coils at the Mercy Women's Center in Fort Smith, Arkansas.

625. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

30. Sherri Helms

626. Plaintiff Sherri Helms is a resident of Warren, Ohio. Plaintiff was born on July 14, 1976. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

627. In or around April of 2009, Plaintiff underwent the Essure procedure in Warren, Ohio.

Post Essure Procedure Condition and Treatment:

628. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, chronic back pain, abdominal pain, chronic fatigue, dental problems, pain during intercourse, and dental problems. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

629. Plaintiff subsequently sought treatment for her symptoms from her physician in Warren, Ohio, but was unable to resolve her symptoms.

630. On or around June 10, 2016, Plaintiff underwent a hysterectomy to have the Essure coils removed at St. Joseph's Hospital in Warren, Ohio.

631. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

31. Tabatha Hicks

632. Plaintiff Tabatha Hicks is a resident of New Marshfield, Ohio. Plaintiff was born on January 17, 1984. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

633. In or around April of 2009, Plaintiff underwent the Essure procedure in Athens, Ohio.

Post Essure Procedure Condition and Treatment:

634. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, chronic back pain, abdominal pain, excessive hair loss, a fibromyalgia diagnosis, and pain during intercourse. Plaintiff never experienced this condition prior to undergoing the Essure procedure.

635. Plaintiff subsequently sought treatment for her symptoms from her physicians in Athens, Ohio but was unable to resolve her symptoms.

636. In or around early 2015, Plaintiff was informed that one of her Essure coils was broken into pieces.

637. In or around February 2015, Plaintiff underwent a hysterectomy to remove her Essure coils at the O'Bleness Hospital in Athens, Ohio.

638. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

32. Javonda Hill

639. Plaintiff Javonda Hill is a resident of Mesquite, Texas. Plaintiff was born on January 24, 1982. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

640. In or around May of 2009, Plaintiff underwent the Essure procedure in Dallas, Texas.

Post Essure Procedure Condition and Treatment:

641. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including chronic pelvic pain, chronic back pain, abdominal pain, heavy menstrual bleeding, excessive rashes, the development of

keloids, and pain during intercourse. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

642. Plaintiff subsequently sought treatment for her symptoms from her physician in Dallas, Texas, but was unable to resolve her symptoms.

643. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

33. Tiffany Hodges

644. Plaintiff Tiffany Hodges is a resident of Pace, Florida. Plaintiff was born on October 1, 1985. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

645. In or around February of 2013, Plaintiff underwent the Essure procedure in Pensacola, Florida.

Post Essure Procedure Condition and Treatment:

646. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, abdominal pain, abdominal bloating, chronic pelvic pain, chronic back pain, excessive weight gain, pain during intercourse, and chronic fatigue. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

647. Plaintiff subsequently sought treatment for her symptoms at the Santa Rosa County Hospital in Milton, Florida, but was unable to resolve her symptoms.

648. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

34. Andrea Hogan

649. Plaintiff Andrea Hogan is a resident of McDonough, Georgia. Plaintiff was born on October 7, 1972. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

650. On or around February 7, 2006, Plaintiff underwent the Essure procedure in Lithonia, Georgia.

Post Essure Procedure Condition and Treatment:

651. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, and abdominal pain. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

652. Plaintiff subsequently sought treatment for her symptoms from her physician in Lithonia, Georgia, but was unable to resolve her symptoms.

653. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

35. Zena Moore Hollins

654. Plaintiff Zena Moore Hollins was a resident of Fort Wayne, Indiana. Plaintiff was born on December 10, 1965. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

655. In or around August of 2009, Plaintiff underwent the Essure procedure in Fort Wayne, Indiana.

Post Essure Procedure Condition and Treatment:

656. Plaintiff's post-procedure period had been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, severe abdominal pain, depression, migraine headaches, mood swings, pain during intercourse, heat flashes, and chronic pelvic pain. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

657. Plaintiff subsequently sought treatment for her symptoms at Parkview Hospital in Fort Wayne, Indiana, and from multiple physicians in Fort Wayne, Indiana and Indianapolis, Indiana, but was unable to resolve her symptoms.

658. On or around March 11, 2015, Plaintiff underwent a DNC procedure and biopsy in an effort to determine the cause of her health problems. At that time, imaging revealed that one of Plaintiff’s Essure coils had migrated and perforated her uterus.

659. The results of the biopsy revealed that Plaintiff had developed uterine cancer.

660. On or around April 17, 2015, Plaintiff underwent total hysterectomy and had her Essure coils removed at the IU Medical Center in Indianapolis, Indiana.

661. On December 17, 2016, Plaintiff succumbed to the cancer that had spread from her uterus and into other areas of her body, and is now deceased.

36. Penny Howard

662. Plaintiff Penny Howard is a resident of Midland, Texas. Plaintiff was born on April 25, 1973. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

663. In or around January of 2015, Plaintiff underwent the Essure procedure in Midland, Texas.

Post Essure Procedure Condition and Treatment:

664. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, chronic back pain, abdominal pain, pain during intercourse, and ovarian cysts. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

665. Plaintiff subsequently sought treatment for her symptoms from her physician in Midland, Texas, but was unable to resolve her symptoms.

666. On or around May 13, 2016, Plaintiff underwent a hysterectomy to remove her Essure coils.

667. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

37. Shatrica Howard

668. Plaintiff Shatrica Howard is a resident of Bloomington, Illinois. Plaintiff was born on September 16, 1987. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

669. On or around June 8, 2011, Plaintiff underwent the Essure procedure in Bloomington, Illinois.

Post Essure Procedure Condition and Treatment:

670. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, uterine cysts, and severe abdominal pain. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

671. Plaintiff subsequently sought treatment for her symptoms at the Advocate BroMenn Medical Center in Bloomington, Illinois, but was unable to resolve her symptoms.

672. On or around January 2, 2014, Plaintiff underwent a hysteroscopy with dilatation and curettage, diagnostic laparoscopy with a ruptured ovarian cyst, and a fluid removal procedure at the Advocate BroMenn Medical Center in Bloomington, Illinois.

673. On or around April 18, 2014, Plaintiff underwent an endometrial ablation at the Advocate BroMenn Medical Center in Bloomington, Illinois.

674. On or around April 21, 2016, Plaintiff underwent a diagnostic laparoscopy and Oophorectomy at the Advocate BroMenn Medical Center in Bloomington, Illinois.

675. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

38. Kristin Huerta

676. Plaintiff Kristin Huerta is a resident of Copperas Cove, Texas. Plaintiff was born on September 9, 1975. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

677. On or around February 24, 2009, Plaintiff underwent the Essure procedure in Hendersonville, Tennessee.

Post Essure Procedure Condition and Treatment:

678. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including chronic pelvic pain, chronic back pain, abdominal pain, heavy menstrual bleeding, pain during intercourse, dental problems, and excessive rashes. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

679. Plaintiff subsequently sought treatment for her symptoms from her physician in Hendersonville, Tennessee, but was unable to resolve her symptoms.

680. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

39. Marci Hughes

681. Plaintiff Marci Hughes is a resident of Oak Park, Illinois. Plaintiff was born on May 25, 2006. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

682. On or around February 23, 2012, Plaintiff underwent the Essure procedure in Chicago, Illinois.

Post Essure Procedure Condition and Treatment:

683. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including weight loss, chronic fatigue, excessive hair loss, depression, anxiety, leg cramps, hip pain, irregular menstrual cycle, nausea, abdominal bloating, brain fog, tingling in her arms and legs, chronic lower back pain, and pain during intercourse. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

684. Plaintiff subsequently sought treatment for her symptoms from her physicians in Chicago, Illinois, but was unable to resolve her symptoms.

685. On or around February 23, 2012, Plaintiff underwent a laparoscopic bilateral salpingectomy to remove her Essure coils at a healthcare facility in Maywood, Illinois.

686. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

40. Kelly Johnson

687. Plaintiff Kelly Johnson is a resident of Pickerington, Ohio. Plaintiff was born on August 30, 1977. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

688. In or around October of 2010, Plaintiff underwent the Essure procedure in Columbus, Ohio.

Post Essure Procedure Condition and Treatment:

689. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including chronic pelvic pain, abdominal pain, and heavy menstrual bleeding. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

690. Plaintiff subsequently sought treatment for her symptoms from her physicians in Columbus, Ohio, but was unable to resolve her symptoms.

691. In or around 2011, Plaintiff underwent surgery to remove her Essure coils the Mount Carmel East Hospital in Columbus, Ohio.

692. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

41. Jenny Johnson

693. Plaintiff Jenny Johnson is a resident of Wheat Ridge, Colorado. Plaintiff was born on October 13, 1978. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

694. In or around March of 2013, Plaintiff underwent the Essure procedure in Denver, Colorado.

Post Essure Procedure Condition and Treatment:

695. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, chronic back pain, excessive rashes, excessive hair loss, abdominal bloating, and abdominal pain. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

696. Plaintiff subsequently sought treatment for her symptoms from her physicians in Denver, Colorado and Wheat Ridge, Colorado, but was unable to resolve her symptoms.

697. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

42. Amber Kamber

698. Plaintiff Amber Kamber is a resident of Santa Nella, California. Plaintiff was born on August 7, 1982. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

699. In or around May of 2014, Plaintiff underwent the Essure procedure in San Jose, California.

Post Essure Procedure Condition and Treatment:

700. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including abdominal pain, chronic pelvic pain, chronic back pain, chronic foot pain, and excessive hair loss. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

701. Plaintiff subsequently sought treatment for her symptoms from her physicians in Gilroy, California; Modesto, California; and Carlsbad, California, but was unable to resolve her symptoms.

702. On or around May 25, 2016, Plaintiff underwent surgery to remove her Essure coils at the Carlsbad Surgery Center in Carlsbad, California.

703. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

43. Kimberly Kearn

704. Plaintiff Kimberly Kearn is a resident of McCalla, Alabama. Plaintiff was born on October 9, 1960. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

705. On or around April 8, 2008, Plaintiff underwent the Essure procedure in Manasquan, New Jersey.

Post Essure Procedure Condition and Treatment:

706. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including chronic pelvic pain, chronic back pain, excessive hair loss, pain during intercourse, a fibromyalgia diagnosis, and a Lichen Planus diagnosis. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

707. Plaintiff subsequently sought treatment for her symptoms from her physicians in Brick, New Jersey; Manasquan, New Jersey; and Pana, Illinois, but was unable to resolve her symptoms.

708. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

44. Wendy Kelley

709. Plaintiff Wendy Kelly is a resident of Pine Bluff, Arkansas. Plaintiff was born on March 12, 1978. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

710. In or around December of 2011, Plaintiff underwent the Essure procedure in Pine Bluff, Arkansas.

Post Essure Procedure Condition and Treatment:

711. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, chronic back pain, abdominal pain, ovarian cysts, and pain during intercourse. Plaintiff never experienced this condition prior to undergoing the Essure procedure.

712. Plaintiff subsequently sought treatment for her symptoms from her physicians in Little Rock, Arkansas and Pine Bluff, Arkansas, but was unable to resolve her symptoms.

713. On or around February 25, 2014, Plaintiff underwent surgery to remove her Essure coils at the UAMS Hospital in Little Rock, Arkansas.

714. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

45. Amber LaPlant

715. Plaintiff Amber LaPlant is a resident of Niagara Falls, New York. Plaintiff was born May 18, 1989. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

716. In or around 2009, Plaintiff underwent the Essure procedure in Brockport, New York. The implanting physician experienced difficulty in placing the Essure coil in Plaintiff’s right fallopian tube, and ultimately removed the right fallopian tube, placing an Essure coil in the left fallopian tube only.

Post Essure Procedure Condition and Treatment:

717. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, abdominal pain, chronic pelvic pain, and chronic back pain. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

718. Plaintiff subsequently sought treatment for her symptoms from her physicians in Brockport, New York, but was unable to resolve her symptoms.

719. In or around April 2010, Plaintiff underwent surgery to remove her remaining Essure coil and remaining fallopian tube.

720. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

46. Kristian Lee

721. Plaintiff Kristian Lee is a resident of Lake Jackson, Texas. Plaintiff was born on March 8, 1990. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

722. In or around February of 2013, Plaintiff underwent the Essure procedure in Longview, Texas.

Post Essure Procedure Condition and Treatment:

723. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, excessive weight gain, abdominal pain, chronic back pain, excessive rashes, excessive hair loss, abdominal bloating, and pain during intercourse. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

724. Plaintiff subsequently sought treatment for her symptoms from her physicians in Tyler, Texas, but was unable to resolve her symptoms.

725. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

47. Elizabeth Little

726. Plaintiff Elizabeth Little is a resident of Scobey, Mississippi. Plaintiff was born on February 15, 1985. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

727. In or around February of 2010, Plaintiff underwent the Essure procedure in Oxford, Mississippi.

Post Essure Procedure Condition and Treatment:

728. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, chronic back pain, abdominal pain, dental problems, unintended pregnancies resulting in multiple miscarriages, metal taste in mouth, abdominal bloating, chronic fatigue, depression, migraine headaches, and pain during

intercourse. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

729. Plaintiff subsequently sought treatment for her symptoms at The Grenada Lake Medical Center in Grenada, Mississippi; Baptist Memorial Hospital, Oxford, Mississippi; and from her physicians in Grenada, Mississippi, but was unable to resolve her symptoms.

730. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

48. Jessica Loudermilk

731. Plaintiff Jessica Loudermilk is a resident of North Lewisburg, Ohio. Plaintiff was born on March 7, 1982. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

732. In or around February of 2006, Plaintiff underwent the Essure procedure in Marysville, Ohio.

Post Essure Procedure Condition and Treatment:

733. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, abdominal pain, chronic pelvic pain, pain during intercourse, excessive weight gain, chronic back pain, chronic fatigue, metal taste in her mouth, severe migraine headaches, excessive hair loss, depression, dental problems, and abdominal bloating. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

734. Plaintiff subsequently sought treatment for her symptoms at Memorial Hospital of Union County in Marysville, Ohio, but was unable to resolve her symptoms.

735. In or around October of 2006, Plaintiff underwent surgery to remove her uterus at the Memorial Hospital of Union County in Marysville, Ohio.

736. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

49. Jennifer Marecle

737. Plaintiff Jennifer Marecle is a resident of Toledo, Ohio. Plaintiff was born on December 1, 1972. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

738. In or around May of 2008, Plaintiff underwent the Essure procedure in Maumee, Ohio.

Post Essure Procedure Condition and Treatment:

739. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including abdominal pain, chronic pelvic pain, pain during intercourse, dental problems, excessive hair loss, abdominal bloating, excessive weight gain, a fibromyalgia diagnosis, and chronic back pain. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

740. Plaintiff subsequently sought treatment for her symptoms from her physicians in Toledo, Ohio and Oregon, Ohio, but was unable to resolve her symptoms.

741. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

50. Starlita McCall

742. Plaintiff Starlita McCall is a resident of Columbus, Ohio. Plaintiff was born on March 8, 1978. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

743. In or around October of 2014, Plaintiff underwent the Essure procedure in Columbus, Ohio.

Post Essure Procedure Condition and Treatment:

744. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, abdominal pain, chronic back pain, pain during intercourse, excessive hair loss, excessive rashes, and frequent bacterial infections. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

745. Plaintiff subsequently sought treatment for her symptoms from her physicians in Columbus, Ohio, but was unable to resolve her symptoms.

746. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

51. Marian Mcgowan

747. Plaintiff Marian Mcgowan is a resident of Houston, Texas. Plaintiff was born on September 6, 1985. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

748. In or around February of 2015, Plaintiff underwent the Essure procedure in Houston, Texas.

Post Essure Procedure Condition and Treatment:

749. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic abdominal pain, chronic pelvic pain, pain during intercourse, excessive hair loss, abdominal bloating, chronic fatigue, and dental problems. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

750. Plaintiff subsequently sought treatment for her symptoms at Park Plaza Hospital in Houston, Texas; Memorial Hermann Texas Medical Center in Houston, Texas; and from her physicians in Houston, Texas, but was unable to resolve her symptoms.

751. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

52. Amy Mendez

752. Plaintiff Amy Mendez is a resident of Eastlake, Ohio. Plaintiff was born on January 28, 1977. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

753. In or around March of 2015, Plaintiff underwent the Essure procedure in Willoughby, Ohio.

Post Essure Procedure Condition and Treatment:

754. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, abdominal pain, chronic pelvic pain, chronic back pain, and excessive hair loss. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

755. Plaintiff subsequently sought treatment for her symptoms at the Lake West Medical Center in Willoughby, Ohio, and from her physicians in Willoughby, Ohio, but was unable to resolve her symptoms.

756. In or around August of 2016 Plaintiff's physician informed her that she was pregnant, and that both Essure coils were still in place. Plaintiff is due on March 10, 2017.

757. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

53. Robin Meyers

758. Plaintiff Robin Meyers is a resident of Olney, Texas. Plaintiff was born on December 16, 1987. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

759. In or around March of 2015, Plaintiff underwent the Essure procedure in Graham, Texas.

Post Essure Procedure Condition and Treatment:

760. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, abdominal pain, pain during intercourse, excessive weight gain, abdominal bloating, and chronic back pain. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

761. Plaintiff subsequently sought treatment for her symptoms from her physicians in Graham, Texas and in Burleson, Texas, but was unable to resolve her symptoms.

762. On or around July 20, 2015, Plaintiff underwent a hysterectomy to remove her Essure coils, at the Texas Health Huguley Hospital in Burleson, Texas.

763. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

54. Dawn Miruka

764. Plaintiff Dawn Miruka is a resident of Vancouver, Washington. Plaintiff was born on November 17, 1974. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

765. In or around August of 2003, Plaintiff underwent the Essure procedure in Portland, Oregon.

Post Essure Procedure Condition and Treatment:

766. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, abdominal pain, a fibromyalgia diagnosis, severe

joint pain, and excessive migraine headaches. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

767. Plaintiff subsequently sought treatment for her symptoms at the Sandy Clinic in Gresham, Oregon; Mount Hood Hospital in Gresham, Oregon; and from her physicians in Portland Oregon, but was unable to resolve her symptoms.

768. In or around November of 2007, Plaintiff underwent a laparoscopic hysterectomy to remove her Essure coils, uterus, and cervix at the Kaiser Hospital in Portland, Oregon.

769. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

55. Jennifer Mott

770. Plaintiff Jennifer Mott is a resident of Hazel Green, Alabama. Plaintiff was born on September 16, 1975. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

771. On or around May 10, 2012, Plaintiff underwent the Essure procedure in Hendersonville, Tennessee.

Post Essure Procedure Condition and Treatment:

772. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, abdominal pain, chronic fatigue, and anxiety. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

773. Plaintiff subsequently sought treatment for her symptoms from her physician in Hendersonville, Tennessee and Huntsville, Alabama, but was unable to resolve her symptoms.

774. In or around April of 2015, Plaintiff underwent surgery to remove her Essure coils at the Crestwood Medical Center in Huntsville, Alabama.

775. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

56. Jane Nagy

776. Plaintiff Jane Nagy is a resident of Notasulga, Alabama. Plaintiff was born on March 21, 1980. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

777. In or around August of 2014, Plaintiff underwent the Essure procedure in Columbus, Georgia.

Post Essure Procedure Condition and Treatment:

778. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, abdominal pain, a fibromyalgia diagnosis, excessive rashes, abdominal bloating, pain during intercourse, persistent migraine headaches, and chronic back pain. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

779. Plaintiff subsequently sought treatment for her symptoms from her physician in Columbus, Georgia, but was unable to resolve her symptoms.

780. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

57. April Neely

781. Plaintiff April Neely is a resident of Amarillo, Texas. Plaintiff was born on January 5, 1984. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

782. In or around March of 2007, Plaintiff underwent the Essure procedure in Amarillo, Texas.

Post Essure Procedure Condition and Treatment:

783. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, abdominal pain, chronic pelvic pain, chronic back pain, pain during intercourse, memory loss, abdominal bloating, and excessive hair loss. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

784. Plaintiff subsequently sought treatment for her symptoms from her physicians in Amarillo, Texas, but was unable to resolve her symptoms.

785. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

58. Michelle Nwankwo

786. Plaintiff Michelle Nwankwo is a resident of Easley, South Carolina. Plaintiff was born on November 7, 1990. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

787. In or around February of 2012, Plaintiff underwent the Essure procedure in Easley, South Carolina.

Post Essure Procedure Condition and Treatment:

788. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including chronic pelvic pain, chronic back pain, pain during intercourse, dental problems, and excessive rashes. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

789. Plaintiff subsequently sought treatment for her symptoms at Baptist Easley Hospital in Easley South Carolina, and from her physician in Easley, South Carolina, but was unable to resolve her symptoms.

790. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

59. Regina O'Neal

791. Plaintiff Regina O'Neal is a resident of Escondido, California. Plaintiff was born on November 27, 1978. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

792. In or around 2009, Plaintiff underwent the Essure procedure in Escondido, California.

Post Essure Procedure Condition and Treatment:

793. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including chronic back pain, abdominal pain, excessive hair loss, pain during intercourse, and chronic pelvic pain. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

794. Plaintiff subsequently sought treatment for her symptoms from her physicians in Escondido, California, but was unable to resolve her symptoms.

795. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

60. Darylyne Osborne

796. Plaintiff Darylyne Osborne is a resident of DeKalb, Illinois. Plaintiff was born on July 5, 1974. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

797. In or around June of 2007, Plaintiff underwent the Essure procedure in Sycamore, Illinois.

Post Essure Procedure Condition and Treatment:

798. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, abdominal pain, chronic pelvic pain, metal taste in mouth, migraine headaches, chronic back pain, pain during intercourse, dental problems, and excessive hair loss. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

799. Plaintiff subsequently sought treatment for her symptoms at Kishwaukee Community Hospital in DeKalb, Illinois, and from her physicians in DeKalb, Illinois, and Chicago, Illinois, but was unable to resolve her symptoms.

800. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

61. Lakesha Owens

801. Plaintiff Lakesha Owens is a resident of Gainesville, Florida. Plaintiff was born on August 16, 1977. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

802. In or around December of 2003, Plaintiff underwent the Essure procedure in Bradenton, Florida.

Post Essure Procedure Condition and Treatment:

803. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding,

chronic pelvic pain, chronic back pain, abdominal pain, pain during intercourse, and frequent bacterial infections. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

804. Plaintiff subsequently sought treatment for her symptoms from her physician in Gainesville, Florida, but was unable to resolve her symptoms.

805. On or around September 11, 2013, Plaintiff underwent a hysterectomy to remove her Essure coils, fallopian tubes, cervix and uterus at the UF Shands Hospital in Gainesville, Florida.

806. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

62. Melissa Pagliarini

807. Plaintiff Melissa Pagliarini is a resident of Warwick, Rhode Island. Plaintiff was born on August 3, 1973. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

808. On or around April 12, 2013, Plaintiff underwent the Essure procedure in Providence, Rhode Island.

Post Essure Procedure Condition and Treatment:

809. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her left Essure coil had migrated and could not be visualized.

810. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, chronic back pain, abdominal pain, abdominal bloating, migraine headaches, chronic fatigue, excessive weight gain, and excessive hair loss. Plaintiff never experienced this condition prior to undergoing the Essure procedure.

811. Plaintiff subsequently sought treatment for her symptoms at Women & Infants Hospital of Rhode Island in Providence, Rhode Island, and from her physicians in East Providence, Rhode Island, but was unable to resolve her symptoms.

812. On or around March 14, 2014, Plaintiff underwent surgery to remove her Essure coils at Women & Infants Hospital of Rhode Island in Providence, Rhode Island. After surgery, Plaintiff was informed that her left Essure was found and removed, although it had migrated.

813. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

63. Kelli Parr

814. Plaintiff Kelli Parr is a resident of Monroeville, Ohio. Plaintiff was born on February 13, 1985. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

815. In or around August of 2009, Plaintiff underwent the Essure procedure in Norwalk, Ohio.

Post Essure Procedure Condition and Treatment:

816. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, abdominal pain, abdominal bloating, and chronic pelvic pain. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

817. Plaintiff subsequently sought treatment for her symptoms with her physicians in Sandusky, Ohio, but was unable to resolve her symptoms.

818. In or around September of 2013, Plaintiff underwent an ablation procedure in an attempt to alleviate her severe and heavy menstrual bleeding.

819. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

64. Crystal Paxson

820. Plaintiff Crystal Paxson is a resident of Lebanon, Ohio. Plaintiff was born on April 16, 1977. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

821. On or around December 18, 2008, Plaintiff underwent the Essure procedure in Springboro, Ohio.

Post Essure Procedure Condition and Treatment:

822. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding,

chronic pelvic pain, abdominal pain, and excessive hair loss. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

823. Plaintiff subsequently sought treatment for her symptoms from her physicians in Hamilton, Ohio, but was unable to resolve her symptoms.

824. On or around June of 2012, Plaintiff underwent surgery to remove her Essure coils at Fort Hamilton Hospital in Hamilton, Ohio.

825. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

65. Princilla Pearson

826. Plaintiff Princilla Pearson is a resident of Taylor, Mississippi. Plaintiff was born on March 7, 1986. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

827. In or around April of 2009, Plaintiff underwent the Essure procedure in Oxford, Mississippi.

Post Essure Procedure Condition and Treatment:

828. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, abdominal pain, chronic back pain, dental problems, pain during intercourse, excessive rashes, and chronic pelvic pain. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

829. Plaintiff subsequently sought treatment for her symptoms from her physicians in Oxford, Mississippi, but was unable to resolve her symptoms.

830. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

66. Ashely Peeples

831. Plaintiff Ashley Peeples is a resident of Norwalk, Ohio. Plaintiff was born on June 11, 1986. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

832. In or around November of 2012, Plaintiff underwent the Essure procedure in Bellevue, Ohio.

Post Essure Procedure Condition and Treatment:

833. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, abdominal pain, chronic pelvic pain, chronic back pain, migraine headaches, depression, chronic fatigue, and pain during intercourse. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

834. Plaintiff subsequently sought treatment for her symptoms from her physicians in Milan, Ohio; Norwalk, Ohio; and Columbus, Ohio, but was unable to resolve her symptoms.

835. On or around September 20, 2016, Plaintiff underwent surgery to remove her Essure coils at Saint Anne Hospital in Columbus, Ohio.

836. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

67. Gracelyn Pruitt

837. Plaintiff Gracelyn Pruitt is a resident of Hector, Arkansas. Plaintiff was born on April 18, 1992. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

838. On or around August 14, 2014, Plaintiff underwent the Essure procedure in Conway, Arkansas. However, only one Essure coil was successfully placed.

839. Plaintiff was required to return to the hospital four days after her initial procedure to have both of fallopian tubes tied, keeping her one Essure coil within her fallopian tube.

Post Essure Procedure Condition and Treatment:

840. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic and abdominal pain, abdominal bloating, pain during intercourse, excessive rashes and hair loss. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

841. Plaintiff subsequently sought treatment for her symptoms at St. Mary’s Hospital in Russellville, Arkansas, and from her physicians in Conway, Arkansas, but was unable to resolve her symptoms.

842. On or around September 15, 2016, Plaintiff underwent surgery to remove her Essure coil, fallopian tubes, cervix, and uterus at the Conway Medical Center in Conway, Arkansas.

843. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

68. Tiffany Queen

844. Plaintiff Tiffany Queen is a resident of St. Louis, Missouri. Plaintiff was born on June 24, 1982. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

845. On or around July 1, 2011, Plaintiff underwent the Essure procedure in St. Louis, Missouri.

Post Essure Procedure Condition and Treatment:

846. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including memory loss, chronic fatigue, depression, heavy menstrual bleeding, chronic pelvic pain, chronic back pain, excessive hair loss, excessive weight gain, ovarian cysts, kidney infections, and abdominal pain. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

847. Plaintiff subsequently sought treatment for her symptoms from her physicians in St. Louis, Missouri, but was unable to resolve her symptoms.

848. On or around January 6, 2017, Plaintiff underwent surgery to remove her Essure coils at the Mercy Hospital in St. Louis, Missouri.

849. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

69. Hilda Ramirez-Villegas

850. Plaintiff Hilda Ramirez-Villegas is a resident of Chicago, Illinois. Plaintiff was born on January 25, 1978. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

851. In or around 2010, Plaintiff underwent the Essure procedure in Chicago, Illinois.

Post Essure Procedure Condition and Treatment:

852. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, abdominal pain, chronic pelvic pain, chronic back pain, pain during intercourse, and excessive hair loss. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

853. Plaintiff subsequently sought treatment for her symptoms from her physician in Chicago, Illinois, but was unable to resolve her symptoms.

854. In or around June of 2015, Plaintiff underwent surgery to remove her Essure coils at the Northwestern Memorial Hospital in Chicago, Illinois.

855. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

70. Patricia Randels

856. Plaintiff Patricia Randels is a resident of Casper, Wyoming. Plaintiff was born on January 23, 1983. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

857. In or around November of 2011, Plaintiff underwent the Essure procedure in Chandler, Arizona.

Post Essure Procedure Condition and Treatment:

858. Plaintiff's post-procedure period has been marked by severe pain and discomfort, including heavy menstrual bleeding, abdominal pain, chronic back pain, chronic pelvic pain, pain during intercourse, chronic fatigue, depression, migraine headaches, excessive weight gain, abdominal bloating, and excessive hair loss. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

859. Plaintiff subsequently sought treatment for her symptoms from her physicians in Casper, Wyoming, but was unable to resolve her symptoms.

860. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

71. Monica Reineir

861. Plaintiff Monica Reineir is a resident of Belgrade, Montana. Plaintiff was born on April 16, 1985. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

862. In or around February of 2008, Plaintiff underwent the Essure procedure in Bozeman, Montana.

Post Essure Procedure Condition and Treatment:

863. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, chronic back pain, dental problems, pain during intercourse, excessive hair loss, and abdominal pain. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

864. Plaintiff subsequently sought treatment for her symptoms from her physicians in Bozeman, Montana, but was unable to resolve her symptoms.

865. In or around October of 2008, Plaintiff underwent a hysterectomy to remove her Essure coils, uterus, fallopian tubes, and cervix at a healthcare facility in Bozeman, Montana.

866. Plaintiff subsequently underwent surgery to remove her right ovary in or around 2012 and then her left ovary in or around 2015, both as a result of ovarian cysts.

867. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

72. Nancy Rivera

868. Plaintiff Nancy Rivera is a resident of Joliet, Illinois. Plaintiff was born on October 27, 1975. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

869. On or around November 30, 2002, Plaintiff underwent the Essure procedure in Oak Lawn, Illinois.

Post Essure Procedure Condition and Treatment:

870. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, chronic back pain, abdominal bloating, anxiety, dental issues, pain during intercourse, excessive hair loss, chronic fatigue, migraine headaches, memory loss, depression,

and excessive rashes. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

871. Plaintiff subsequently sought treatment for her symptoms from her physicians in Joliet, Illinois; Chicago Ridge, Illinois; and Bridgeview, Illinois, but was unable to resolve her symptoms.

872. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

73. Vanessa Rivera

873. Plaintiff Vanessa Rivera is a resident of Casselberry, Florida. Plaintiff was born on May 8, 1985. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

874. In or around March of 2014, Plaintiff underwent the Essure procedure in Altamonte, Florida.

Post Essure Procedure Condition and Treatment:

875. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, abdominal pain, chronic back pain, excessive hair loss, migraine headaches, and pain during intercourse. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

876. Plaintiff subsequently sought treatment for her symptoms from her physicians in Casselberry, Florida, but was unable to resolve her symptoms.

877. On or around August 30, 2016, Plaintiff underwent surgery to remove a ovarian cyst at the Altamonte Hospital in Altamonte, Florida.

878. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

74. Asya Rodgers

879. Plaintiff Asya Rodgers is a resident of Houston, Texas. Plaintiff was born on January 28, 1979. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

880. In or around October of 2008, Plaintiff underwent the Essure procedure in Austell, Georgia.

Post Essure Procedure Condition and Treatment:

881. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, chronic back pain, excessive weight gain, depression, and severe abdominal pain. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

882. Plaintiff subsequently sought treatment for her symptoms at Memorial Herman Hospital in Houston, Texas, and from her physicians in Conyers, Georgia and Houston, Texas, but was unable to resolve her symptoms.

883. On or around June 22, 2016, Plaintiff underwent a CT scan at the Memorial Herman Hospital in Houston, Texas in an effort to determine the cause of her health problems. That CT scan revealed that Plaintiff's right Essure coil had migrated partially into her endometrial canal.

884. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

75. Ashley Rogers

885. Plaintiff Ashley Rogers is a resident of Malvern, Ohio. Plaintiff was born on April 27, 1985. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

886. In or around 2011, Plaintiff underwent the Essure procedure in Canton, Ohio.

Post Essure Procedure Condition and Treatment:

887. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, chronic back pain, abdominal pain, pain during intercourse, and excessive hair loss. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

888. Plaintiff subsequently sought treatment for her symptoms from her physician in Carrolton, Ohio, but was unable to resolve her symptoms.

889. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

76. Tabitha Ross

890. Plaintiff Tabitha Ross is a resident of Austin, Texas. Plaintiff was born on May 28, 1986. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

891. In or around August of 2012, Plaintiff underwent the Essure procedure in Austin, Texas.

Post Essure Procedure Condition and Treatment:

892. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, abdominal pain, chronic pelvic pain, pain during intercourse, excessive weight gain, abdominal bloating, and excessive hair loss. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

893. Plaintiff subsequently sought treatment for her symptoms at South Austin Hospital in Austin, Texas, and from her physicians in Austin, Texas, but was unable to resolve her symptoms.

894. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

77. Amy Rutan

895. Plaintiff Amy Rutan is a resident of Lathrop, California. Plaintiff was born on November 4, 1979. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

896. In or around 2008, Plaintiff underwent the Essure procedure in Martinez, California.

Post Essure Procedure Condition and Treatment:

897. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, abdominal pain, chronic back pain, excessive hair loss, pain during intercourse, excessive weight gain, abdominal bloating, migraine headaches, depression, chronic fatigue, and dental problems. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

898. Plaintiff subsequently sought treatment for her symptoms at St. Joseph’s Medical Center in Stockton, California, and from her physicians in Pleasanton, California; Tracy, California; Stockton, California; and Martinez, California, but was unable to resolve her symptoms.

899. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

78. Cristina Ruvalcaba

900. Plaintiff Christina Ruvalcaba is a resident of Madera, California. Plaintiff was born on April 5, 1981. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

901. On or around August 28, 2015, Plaintiff underwent the Essure procedure in Fresno, California.

Post Essure Procedure Condition and Treatment:

902. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including chronic pelvic pain, abdominal pain, chronic back pain, excessive hair loss, pain during intercourse, chronic fatigue, abdominal bloating, migraine headaches, depression, metal taste in mouth, anxiety, and dental issues. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

903. Plaintiff subsequently sought treatment for her symptoms at the Kaiser Hospital in Fresno, California on multiple occasions, but was unable to resolve her symptoms.

904. On or around September 6, 2016, Plaintiff underwent surgery to remove her Essure coils and fallopian tubes at the Kaiser Permanente Hospital in Fresno, California.

905. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

79. Sophia Silva

906. Plaintiff Sophia Silva is a resident of McAllen, Texas. Plaintiff was born on December 29, 1983. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

907. On or around June 29, 2012, Plaintiff underwent the Essure procedure in McAllen, Texas.

Post Essure Procedure Condition and Treatment:

908. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including chronic pelvic pain, chronic back pain, abdominal pain, abdominal bloating, dental problems, anxiety, metal taste in mouth, severe migraine headaches, depression, chronic fatigue, and excessive weight gain. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

909. Plaintiff subsequently sought treatment for her symptoms from her physicians in Edinburg, Texas and Mission, Texas, but was unable to resolve her symptoms.

910. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

80. Hollie Sledge

911. Plaintiff Hollie Sledge is a resident of Wonder Lake, Illinois. Plaintiff was born on January 2, 1987. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

912. In or around October of 2014, Plaintiff underwent the Essure procedure in Wonder Lake, Illinois.

Post Essure Procedure Condition and Treatment:

913. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, excessive hair loss, and pain during intercourse. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

914. Plaintiff subsequently sought treatment for her symptoms from her physician in Wonder Lake, Illinois, but was unable to resolve her symptoms.

915. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

81. Jessica Strickland

916. Plaintiff Jessica Strickland is a resident of Zebulon, North Carolina. Plaintiff was born on October 1, 1980. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

917. In or around March of 2012, Plaintiff underwent the Essure procedure in Wilson, North Carolina.

Post Essure Procedure Condition and Treatment:

918. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, abdominal pain, chronic back pain, chronic pelvic

pain, abdominal bloating, pain during intercourse, and dental problems. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

919. Plaintiff subsequently sought treatment for her symptoms at Franklin County Regional Medical Center in Louisburg, North Carolina and at Nash General Hospital in Nash County, North Carolina, but was unable to resolve her symptoms.

920. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

82. Tina Strickland

921. Plaintiff Tina Strickland is a resident of Live Oak, Florida. Plaintiff was born on October 6, 1971. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

922. On or around September 13, 2013, Plaintiff underwent the Essure procedure in Gainesville, Florida.

Post Essure Procedure Condition and Treatment:

923. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including chronic back pain, chronic pelvic pain, abdominal pain, and frequent urinary tract infections. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

924. Plaintiff subsequently sought treatment for her symptoms from her physicians in Gainesville, Florida, but was unable to resolve her symptoms.

925. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

83. Amanda Sullivan

926. Plaintiff Amanda Sullivan is a resident of Colorado Springs, Colorado. Plaintiff was born on March 12, 1986. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

927. In or around February of 2011, Plaintiff underwent the Essure procedure in Colorado Springs, Colorado.

Post Essure Procedure Condition and Treatment:

928. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, abdominal pain, chronic back pain, chronic pelvic pain, excessive rashes, pain during intercourse, abdominal bloating, frequent infections, excessive weight gain, and migraine headaches. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

929. Plaintiff subsequently sought treatment for her symptoms from her physician in Colorado Springs, Colorado, but was unable to resolve her symptoms.

930. In or around December of 2013, Plaintiff underwent a hysterectomy to remove her Essure coils at the Memorial Hospital Central in Colorado Springs, Colorado.

931. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

84. Kenesha Thomas

932. Plaintiff Kenesha Thomas is a resident of Houston, Texas. Plaintiff was born on August 26, 1982. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

933. In or around August 2008, Plaintiff underwent the Essure procedure in Houston, Texas.

Post Essure Procedure Condition and Treatment:

934. Plaintiff’s post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, abdominal pain, chronic back pain, chronic pelvic pain, excessive rashes, excessive hair loss, pain during intercourse, and dental problems. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

935. Plaintiff subsequently sought treatment for her symptoms from her physician in Houston, Texas, but was unable to resolve her symptoms.

936. In or around 2009, Plaintiff underwent surgery to remove her Essure coils, fallopian tubes, and her uterus at the Cypress Fairbanks Medical Center, in Houston Texas.

937. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

85. Marcelina Turcios

938. Plaintiff Marcelina Turcios is a resident of Houston, Texas. Plaintiff was born on March 12, 1994. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

939. In or around June of 2012, Plaintiff underwent the Essure procedure in Houston, Texas.

Post Essure Procedure Condition and Treatment:

940. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, and abdominal pain. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

941. Plaintiff subsequently sought treatment for her symptoms from her physicians in Houston, Texas, but was unable to resolve her symptoms.

942. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

86. Tammy Ward

943. Plaintiff Tammy Ward is a resident of Marion, Ohio. Plaintiff was born on March 26, 1986. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

944. In or around June of 2007, Plaintiff underwent the Essure procedure in Louisa, Kentucky.

Post Essure Procedure Condition and Treatment:

945. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including chronic pelvic pain and migraine headaches. Plaintiff never experienced this condition prior to undergoing the Essure procedure.

946. Plaintiff subsequently sought treatment for her symptoms from her physician in Marion, Ohio, but was unable to resolve her symptoms.

947. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

87. Erica Ware

948. Plaintiff Erica Ware is a resident of St. Louis, Missouri. Plaintiff was born on August 14, 1979. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

949. In or around June of 2013, Plaintiff underwent the Essure procedure in Chesterfield, Missouri.

Post Essure Procedure Condition and Treatment:

950. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, abdominal pain, excessive hair loss, and chronic back pain. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

951. Plaintiff subsequently sought treatment for her symptoms at Christian Hospital in St. Louis, Missouri, and from her physicians in St. Louis, Missouri, but was unable to resolve her symptoms.

952. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

88. Nina Weaver

953. Plaintiff Nina Weaver is a resident of Harrisburg, Pennsylvania. Plaintiff was born on June 27, 1981. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

954. On or around December 8, 2011, Plaintiff underwent the Essure procedure in Harrisburg, Pennsylvania.

Post Essure Procedure Condition and Treatment:

955. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding with clotting, abdominal pain, chronic pelvic pain, chronic back pain, and excessive hair loss. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

956. Plaintiff subsequently sought treatment for her symptoms from her physicians in Hershey, Pennsylvania and Harrisburg, Pennsylvania, but was unable to resolve her symptoms.

957. On or around May 27, 2016, Plaintiff underwent a hysterectomy to remove her Essure coils at the Penn State Health Milton S. Hershey Medical Center in Hershey, Pennsylvania.

958. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

89. Felicia Weber

959. Plaintiff Felicia Weber is a resident of Gouverneur, New York. Plaintiff was born on August 17, 1982. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

960. On or around May 20, 2005, Plaintiff underwent the Essure procedure in Syracuse, New York.

Post Essure Procedure Condition and Treatment:

961. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, pain during intercourse, chronic pelvic pain, chronic back pain, dental problems, abdominal bloating, anxiety, a metallic taste in her mouth, and migraine headaches. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

962. Plaintiff subsequently sought treatment for her symptoms from her physicians in Oswego, New York and in Syracuse, New York, but was unable to resolve her symptoms.

963. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

90. Michelle Weedman

964. Plaintiff Michelle Weedman is a resident of Byrnes Mill, Missouri. Plaintiff was born on August 24, 1983. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

965. On or around April 11, 2012, Plaintiff underwent the Essure procedure in St. Louis, Missouri.

Post Essure Procedure Condition and Treatment:

966. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including memory loss, abdominal pain, heavy menstrual bleeding, and pain during intercourse. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

967. Plaintiff subsequently sought treatment for her symptoms from her physicians in St. Louis, Missouri, but was unable to resolve her symptoms.

968. On or around May 27, 2016, Plaintiff underwent a hysterectomy to remove her Essure coils at a healthcare facility in St. Louis, Missouri.

969. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

91. Lavena Wilkerson

970. Plaintiff Lavena Wilkerson is a resident of Sarcoxie, Missouri. Plaintiff was born on January 4, 1977. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

971. On or around August 6, 2009, Plaintiff underwent the Essure procedure in Winfield, Kansas.

Post Essure Procedure Condition and Treatment:

972. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, abdominal pain, abdominal bloating, depression, chronic fatigue, memory loss, chronic pelvic pain, chronic back pain, pain during intercourse, excessive weight gain, and excessive rashes. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

973. Plaintiff subsequently sought treatment for her symptoms at William Newton Hospital in Winfield, Kansas; Mercy Hospital Joplin in Joplin, Missouri; and from her physicians in Winfield, Kansas and Joplin, Missouri, but was unable to resolve her symptoms.

974. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

92. Melissa Williams

975. Plaintiff Melissa Williams is a resident of Blaine, Minnesota. Plaintiff was born on July 12, 1972. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

976. In or around August 2010, Plaintiff underwent the Essure procedure in Minnetonka, Minnesota. However, Plaintiff's implanting physician was only able to place one Essure coil in one of her fallopian tubes.

977. Plaintiff then underwent a second Essure procedure on August 26, 2010 in Edina, Minnesota, where Plaintiff's implanting physician placed two Essure coils into the fallopian tube that he was not able to place an Essure coil in during Plaintiff's initial Essure procedure.

Post Essure Procedure Condition and Treatment:

978. Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, chronic back pain, abdominal pain, anxiety, metal taste in mouth, migraine headaches, and chronic fatigue. Plaintiff never experienced this condition prior to undergoing the Essure procedure.

979. Plaintiff subsequently sought treatment for her symptoms from her physicians in Eden Prairie, Minnesota and Minnetonka, Minnesota, but was unable to resolve her symptoms.

980. In or around 2011, Plaintiff discovered she was pregnant and later gave birth to a child on December 30, 2012.

981. In or around February 2013, Plaintiff underwent surgery to remove her Essure coils at the Fairview Southdale Hospital in Edina, Minnesota.

982. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

93. Johnnie Williams

983. Plaintiff Johnnie Williams is a resident of Columbus, Ohio. Plaintiff was born on December 28, 1981. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

984. On or around June 5, 2010, Plaintiff underwent the Essure procedure in Columbus, Ohio.

Post Essure Procedure Condition and Treatment:

985. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, chronic back pain, abdominal pain, abdominal bloating, pain during

intercourse, excessive weight gain, excessive rashes, migraine headaches, depression, dental problems, and excessive hair loss. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

986. Plaintiff subsequently sought treatment for her symptoms from her physicians in Columbus, Ohio, but was unable to resolve her symptoms.

987. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

94. Charli Zovak

988. Plaintiff Charli Zovak is a resident of Holiday Island, Arkansas. Plaintiff was born on August 1, 1987. Plaintiff underwent the Essure procedure and was implanted with the Essure device.

Initial Essure Procedure:

989. In or around May of 2010, Plaintiff underwent the Essure procedure in Johnson, Arkansas.

Post Essure Procedure Condition and Treatment:

990. Shortly after undergoing the Essure procedure, an HSG test was performed and Plaintiff was advised that her coils were properly placed. However, Plaintiff's post-procedure period has been marked by increasingly severe pain and discomfort, including heavy menstrual bleeding, chronic pelvic pain, abdominal pain, chronic back pain, pain during intercourse, dental problems, and excessive rashes. Plaintiff never experienced any of these conditions prior to undergoing the Essure procedure.

991. Plaintiff subsequently sought treatment for her symptoms at Mercy Hospital in Berryville, Arkansas, and from her physicians in Berryville, Arkansas, but was unable to resolve her symptoms.

992. On or around August 2, 2014, Plaintiff underwent a hysterectomy to remove her Essure coils at Mercy Hospital in Muskogee, Oklahoma.

993. Plaintiff is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious and permanent injuries.

VIII. AGENCY, ALTER-EGO, JOINT VENTURE, AND CONSPIRACY

994. At all times herein mentioned, the Defendants were fully informed of the actions of their agents, representatives, contractors, and/or employees, and thereafter, no officer, director or

managing agent of the Defendants repudiated those actions. The failure to repudiate constituted adoption and approval of said actions, and all Defendants and each of them thereby ratified those actions.

995. At all times mentioned herein, there existed (and still exists) a unity of interest between certain Defendants and other certain Defendants such that any individuality and separateness between the certain Defendants has ceased, and these Defendants are the alter-egos of the other certain Defendants and exerted control over those Defendants. Defendant Bayer AG controlled its wholly owned subsidiaries to such a degree and in such a manner as to render them more business units and to make them merely an agency, instrumentality, adjunct, or its alter ego. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from other certain Defendants will permit an abuse of the corporate privilege, sanction a fraud, and/or promote injustice.

996. Each of the Defendants herein expressly or impliedly agreed to work with and assist each other Defendant and unnamed parties, toward the common purpose of promoting, recommending, and selling Essure and toward the common interest of pecuniary gain.

997. Each of the Defendants herein performed the acts and omissions described herein in concert with the other Defendants herein and/or pursuant to a common design with the other Defendants herein.

998. Each of the Defendants herein knew the acts and omissions of the other Defendants herein constituted a breach of duty, and yet, each Defendant herein provided each other Defendant substantial assistance and/or encouragement.

999. Each of the Defendants herein provided substantial assistance to the other Defendants herein in accomplishing the intentional and tortious conduct described herein, and each Defendants' conduct, even when separately considered, constitutes a breach of duties owed to the Plaintiffs.

1000. At all times herein mentioned, each of the Bayer Defendants were engaged in the business of and/or were a successor in interest to and/or affiliated with/associated with/indistinguishable from entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing, advertising for sale, and/or selling Essure device for use by the Plaintiffs and the Plaintiffs' physicians. As such, each of the

Bayer Defendants is individually, as well as jointly and severally, liable to the Plaintiffs for the Plaintiffs' damages.

1001. The conduct of the Defendants herein caused the Plaintiffs' harm as described herein. The Plaintiffs' harm is not in any way attributable to any fault of the Plaintiffs'. Uncertainty may exist regarding which Defendant(s) and/or combination of Defendants caused the Plaintiffs' harm. The Defendants possess superior knowledge and information regarding which Defendant(s) and/or combination of Defendants caused the Plaintiffs' injuries. Thus, the burden of proof is upon each Defendant to prove the Defendant did not cause the Plaintiffs' harm as described herein.

1002. Thus, the burden of proof should be upon each Defendant to prove that the Defendant has not caused the harms suffered by the Plaintiffs.

1003. Due to the above, each Cause of Action named below is asserted against each Defendant herein, jointly and severally, even if each and every Defendant herein is not specifically identified as to each and every count.

IX. PLAINTIFFS ARE ENTITLED TO PUNITIVE DAMAGES

1004. Plaintiffs repeat and incorporate by reference all other paragraphs of this Petition as if fully set forth herein and further alleges as follows:

1005. As a result of Conceptus and Bayer's oppression, fraudulent concealment, wantonness, malice, and reckless disregard for Plaintiffs' safety, Plaintiffs are entitled to punitive or exemplary damages to the fullest extent necessary as plead in detail below.

X. CLAIMS FOR RELIEF

a. FIRST CAUSE OF ACTION

Negligence

1006. Plaintiffs repeat and incorporate by reference all other paragraphs of this Petition as if fully set forth herein and further alleges as follows:

1007. Conceptus and Bayer were and are under a continuing duty to comply with federal requirements, including the PMA, its Supplements, the Conditions of Approval, and with the FDCA in the manufacture, development, design, marketing, labeling, distributing, and sale of Essure and its implementing.

1008. Conceptus and Bayer concealed material information related to the safety of the Essure device and deceptively and falsely underreported the dangerous propensities and increased risks of Essure.

1009. Defendants' Conditions of Approval expressly provided that "continued approval of this PMA is contingent upon the submission of post-approval reports required under 21 C.F.R. § 814.84…"

1010. The information required to be submitted included, in part, information that is known or reasonably should be known to the applicant and shall include "unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices."

1011. It was the duty of Conceptus and Bayer to comply with federal law, the FDCA, the MDA and the regulations, notwithstanding this duty, Conceptus and Bayer violated federal law, the FDCA, the MDA, and the regulations, including but not limited to, in one or more of the following ways:

A) 21 U.S.C. § 352(a) because Conceptus and Bayer promoted for sale of misbranded and adulterated products because the Essure label is false and misleading because Essure is not a safer and more effective method of permanent sterilization than alternative methods, evidenced by the over 10,000 reported adverse events consisting of serious injuries and pregnancies, by the numerous Essure studies consisting of thousands of women reporting that patients who undergo the Essure procedure are more likely to experience injuries and complications which require or will require surgical intervention or re-operation, and by the over 30,000 unreported complaints contained in Conceptus and Bayer's complaint files.

B) 21 U.S.C. § 331(a) because Conceptus and Bayer introduced into interstate commerce a medical device that was misbranded, for the reasons set forth herein.

C) 21 U.S.C. § 352(q) because Conceptus and Bayer created and distributed false and misleading advertising for Essure which is a "Restricted Device" because Essure is not a safer and more effective method of permanent sterilization than alternative methods, evidenced by the over 10,000 reported adverse events consisting of serious injuries and pregnancies, by the numerous Essure studies consisting of thousands of women reporting that patients who undergo the Essure procedure are more likely to experience injuries and complications which require or will require surgical intervention or re-operation, and by the over 30,000 unreported complaints contained in Conceptus and Bayer's complaint files.

D) 21 C.F.R. § 820.3(z)(x), 21 C.F.R. § 820.22, 21 C.F.R. § 820.5, 21 C.F.R. §820.1(a), 21 C.F.R. § 820.22, 21 C.F.R. § 820.160(a), 21 C.F.R. § 820.198(a) and 21 C.F.R. § 820.170(a) because Conceptus and Bayer failed to comply with the general quality control standards found in these regulations.

E) 21 C.F.R. § 803.50; 21 C.F.R. § 814.80, and 21 U.S.C. § 360i(a), because as discussed in detail above, Conceptus and Bayer failed to report and/or timely report adverse events, including but not limited to, complaints of device migration, device fracture/breakage, perforation, heavy menstrual cycle bleeding, and long-term chronic pain, all of which are serious injuries or may lead to a serious injury because such injuries required Plaintiffs to undergo surgical intervention to prevent further injury and/or may require Plaintiffs to undergo surgical intervention in the future to prevent further injury.

F) 21 C.F.R. § 814.84(b)(2) because as discussed in detail above, Conceptus and Bayer failed to report new clinical investigations and/or scientific studies concerning the Essure device about which Conceptus and Bayer knew or reasonably should have

known about, including but not limited to the Cornell study, the article published in the online medical journal Conception, and the eight (8) articles describing 12 cases of Essure abdominal migration published between January 2002 and December 2013 that were never reported to the FDA.

G) 21 U.S.C. §§ 360(q); 360(r) because Conceptus and Bayer created and distributed false and misleading advertising, including but not limited to representations and warranties regarding the risks, safety, recovery time, and effectiveness of Essure in order to convince physicians and patients to use Essure over other methods of permanent birth control, thereby gaining market share.

H) 21 C.F.R. § 820.198 because Conceptus and Bayer failed to establish and maintain procedures for implementing corrective and preventative action in response to, *inter alia*, complaints of, but not limited to, device migration, device fracture/breakage, perforation, heavy menstrual cycle bleeding, long-term chronic pain, and other quality problems associated with the Essure device.

I) 21 C.F.R. § 820.198 and 21 C.F.R. § 803.3 because Conceptus and Bayer (1) failed to appropriately respond to adverse incident reports, including but not limited to, reports of device migration outside of the fallopian tubes and/or device fracture/breakage, which strongly indicated the Essure device was malfunctioning or otherwise not responding to its Design Objective Intent, which was to remain permanently in Plaintiffs' fallopian tubes, and (2) Conceptus and Bayer continued to sell Essure into the stream of interstate commerce when they knew, or should have known, that the Essure was malfunctioning or otherwise not responding to its Design Objective Intent.

J) 21 C.F.R. § 814.80 because Conceptus and Bayer manufactured, packaged, stored, labeled, distributed, and/or advertised in a manner that is inconsistent with the conditions for approval specified in the PMA approval for it.

K) 21 C.F.R. § 820.30 because Conceptus and Bayer failed to establish and maintain procedures for validating the device design, including testing of production units under actual or simulated use conditions, creation of a risk plan, and conducting risk analyses, upon obtaining knowledge of device failures including but not limited to perforation, device migration, and/or device fracture/breakage.

L) 21 C.F.R. § 820.100 because upon obtaining knowledge of device failure modes, Conceptus and Bayer: (1) failed to routinely analyze complaints and other sources of quality data to identify existing and potential causes of nonconforming products or other quality problems and failed to use appropriate statistical methodology to detect recurring quality problems, including but not limited to, complaints of perforation, device migration, and/or device fracture/breakage; (2) failed to investigate the cause of nonconformities relating to product, processes, and the quality system; (3) failed to identify the action(s) needed to correct and prevent recurrence of such nonconforming product and other quality problems; and (4) failed to take any and all Corrective and Preventative Actions ("CAPA") necessary to address non-conformance and other internal quality control issues.

M) 21 C.F.R. § 820.70 because Conceptus and Bayer failed to establish Quality Management Systems ("QMS") procedures to assess potential causes of non-conforming products, including but not limited to device migration, device fracture/breakage, and/or latent manufacturing defects, and other quality problems with the Essure device.

N) 21 C.F.R. § 814.39 because Conceptus and Bayer failed to submit and/or timely submit a PMA supplement and make a labeling change to add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association; such evidence is the thousands of reported and unreported adverse events consisting of serious injuries and pregnancies, by the numerous Essure studies consisting of thousands of women reporting that patients who undergo the Essure procedure are more likely to

experience injuries and complications which require or will require surgical intervention or re-operation, and by the over 30,000 unreported complaints contained in Conceptus and Bayer's complaint files.

1012. As a direct and proximate result of Conceptus and Bayer's violations of one or more of the above federal statutory and regulatory standards of care, the Essure device was implanted in Plaintiffs and Plaintiffs were caused to endure a serious injury, as defined in 21 C.F.R. § 803.3. Plaintiffs were caused to suffer, and will suffer in the future, injuries including, but not limited to pain, suffering, lost wages, disability, disfigurement, legal obligations for hospital, medical, nursing, rehabilitative, and other medical services and treatment.

1013. Conceptus and Bayer failed to exercise reasonable care in the manufacture, sale, testing, quality assurance, quality control, and/or distribution of Essure.

1014. This cause of action is based entirely on the contention that Conceptus and Bayer violated federal safety statutes and regulations. Plaintiffs do not bring the underlying action as an implied statutory cause of action but rather Plaintiffs are pursuing parallel state common law claims based on Conceptus and Bayer’s violations of the applicable federal regulations. Plaintiffs are not seeking to enforce these provisions in this action. Likewise, Plaintiffs are not suing merely because Conceptus and Bayer’s conduct violates these provisions. Rather Plaintiffs are alleging that Conceptus and Bayer’s conduct that violates these provisions also violates parallel state laws.

1015. Conceptus and Bayer’s violations of the aforementioned federal statutes and regulations establish a *prima facie* case of negligence in tort under state common law.

1016. Thus, for violation of federal law including but not limited to the FDCA, the MDA and relevant regulations which results in an unreasonably dangerous product proximately causing injuries there already exists a money damages remedy under state common law.

1017. Conceptus and Bayer owed Plaintiffs and Plaintiffs' physicians the duty to exercise reasonable or ordinary care under the circumstances, in light of the generally-recognized and prevailing best scientific knowledge.

1018. Conceptus and Bayer had a confidential and special relationship with Plaintiffs due to their vastly superior knowledge of the health and safety risks relating to Essure.

1019. As a result, Conceptus and Bayer had an affirmative duty to fully and adequately warn Plaintiffs and Plaintiffs' physicians of the true health and safety risks related to the use of Essure. Independent of any special relationship of confidence or trust, Conceptus and Bayer had a duty not to conceal the dangers of Essure from Plaintiffs and Plaintiffs' physicians.

1020. Misrepresentations made by Conceptus and Bayer about the health and safety of Essure independently imposed a duty upon Conceptus and Bayer to fully and accurately disclose to Plaintiffs and Plaintiffs' physicians the true health and safety risks related to Essure.

1021. Through the conduct described in the foregoing and subsequent paragraphs of this Petition, Conceptus and Bayer breached their duties to Plaintiffs and to Plaintiffs' physicians.

1022. The following sub-paragraphs summarize, *inter alia*, Conceptus and Bayer's breaches of duties to Plaintiffs and Plaintiffs' physicians and describe categories of acts or omissions constituting breaches of duty by Conceptus and Bayer. Each and/or any of these acts or omissions establishes an independent basis for their liability in negligence:

A) Unreasonable and improper promotion and marketing of Essure to physicians;

B) Failure to warn the FDA, Plaintiffs and Plaintiffs' physicians of the dangers associated with the increased risks and dangers of Essure; or

C) Failure to exercise reasonable care by not complying with federal law and regulations applicable to the manufacture, sale, and marketing of Essure.

1023. Under federal law, Conceptus and Bayer had a continuing duty to monitor the product after premarket approval and to discover and report to the FDA any complaints about the product's performance and any adverse health consequences that are or may be attributable to the product.

1024. Conceptus and Bayer violated its duties under federal law to report adverse event information to the FDA. Because Conceptus and Bayer failed to comply with their duty under federal law, they breached their duty to use reasonable care under parallel state laws.

1025. Settled state common laws protect the safety and health of its citizens by imposing a general duty of reasonable care on product manufacturers. Moreover, state common laws include causes of action for failure to warn. A product is unreasonably dangerous in the absence of adequate warnings under applicable state common laws.

1026. Conceptus and Bayer failed to use reasonable care and failed to adequately warn as to the increased risks and dangers of Essure. As a result of these wrongful actions, the Plaintiffs were caused to suffer severe injuries and to incur significant damages.

1027. Conceptus and Bayer knew, or should have known, that due to their failure to use reasonable care, Plaintiffs and Plaintiffs' physicians would use and did use Essure to the detriment of Plaintiffs' health, safety and well-being.

1028. As the direct, producing, proximate and legal cause and result of Conceptus and Bayer's negligence, Plaintiffs suffered severe injuries.

1029. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

1030. Conceptus and Bayer's conduct, as alleged above, was malicious, intentional and outrageous and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiffs and warrants an award of punitive damages.

b. SECOND CAUSE OF ACTION

Negligence Per Se

1031. Plaintiffs repeat and incorporate by reference all other paragraphs of this Petition as if fully set forth herein and further alleges as follows:

1032. It was the duty of Conceptus and Bayer to comply with federal law, the FDCA, the MDA and the regulations, notwithstanding this duty, Conceptus and Bayer violated federal law, the FDCA, the MDA, and the regulations, including but not limited to, in one or more of the following ways:

A) 21 U.S.C. § 352(a) because Conceptus and Bayer promoted for sale of misbranded and adulterated products because the Essure label is false and misleading because Essure is not a safer and more effective method of permanent sterilization than alternative methods, evidenced by the over 10,000 reported adverse events consisting of serious injuries and pregnancies, by the numerous Essure studies consisting of thousands of women reporting that patients who undergo the Essure procedure are more likely to experience injuries and complications which require or will require surgical intervention or re-operation, and by the over 30,000 unreported complaints contained in Conceptus and Bayer's complaint files.

B) 21 U.S.C. § 331(a) because Conceptus and Bayer introduced into interstate commerce a medical device that was misbranded, for the reasons set forth herein.

C) 21 U.S.C. § 352(q) because Conceptus and Bayer created and distributed false and misleading advertising for Essure which is a "Restricted Device" because Essure is not a safer and more effective method of permanent sterilization than alternative methods, evidenced by the over 10,000 reported adverse events consisting of serious injuries and pregnancies, by the numerous Essure studies consisting of thousands of women reporting that patients who undergo the Essure procedure are more likely to experience injuries and complications which require or will require surgical intervention or re-operation, and by the over 30,000 unreported complaints contained in Conceptus and Bayer's complaint files.

D) 21 C.F.R. § 820.3(z)(x), 21 C.F.R. § 820.22, 21 C.F.R. § 820.5, 21 C.F.R. §820.1(a), 21 C.F.R. § 820.22, 21 C.F.R. § 820.160(a), 21 C.F.R. § 820.198(a) and 21 C.F.R. § 820.170(a) because Conceptus and Bayer failed to comply with the general quality control standards found in these regulations.

E) 21 C.F.R. § 803.50; 21 C.F.R. § 814.80, and 21 U.S.C. § 360i(a), because as discussed in detail above, Conceptus and Bayer failed to report and/or timely report adverse events, including but not limited to, complaints of device migration, device fracture/breakage, perforation, heavy menstrual cycle bleeding, and long-term

chronic pain, all of which are serious injuries or may lead to a serious injury because such injuries required Plaintiffs to undergo surgical intervention to prevent further injury and/or may require Plaintiffs to undergo surgical intervention in the future to prevent further injury.

F) 21 C.F.R. § 814.84(b)(2) because as discussed in detail above, Conceptus and Bayer failed to report new clinical investigations and/or scientific studies concerning the Essure device about which Conceptus and Bayer knew or reasonably should have known about, including but not limited to the Cornell study, the article published in the online medical journal Conception, and the eight (8) articles describing 12 cases of Essure abdominal migration published between January 2002 and December 2013 that were never reported to the FDA.

G) 21 U.S.C. §§ 360(q); 360(r) because Conceptus and Bayer created and distributed false and misleading advertising, including but not limited to representations and warranties regarding the risks, safety, recovery time, and effectiveness of Essure in order to convince physicians and patients to use Essure over other methods of permanent birth control, thereby gaining market share.

H) 21 C.F.R. § 820.198 because Conceptus and Bayer failed to establish and maintain procedures for implementing corrective and preventative action in response to, *inter alia*, complaints of, but not limited to, device migration, device fracture/breakage, perforation, heavy menstrual cycle bleeding, long-term chronic pain, and other quality problems associated with the Essure device.

I) 21 C.F.R. § 820.198 and 21 C.F.R. § 803.3 because Conceptus and Bayer (1) failed to appropriately respond to adverse incident reports, including but not limited to, reports of device migration outside of the fallopian tubes and/or device fracture/breakage, which strongly indicated the Essure device was malfunctioning or otherwise not responding to its Design Objective Intent, which was to remain permanently in Plaintiffs' fallopian tubes, and (2) Conceptus and Bayer continued to sell Essure into the stream of interstate commerce when they knew, or should have known, that the Essure was malfunctioning or otherwise not responding to its Design Objective Intent.

J) 21 C.F.R. § 814.80 because Conceptus and Bayer manufactured, packaged, stored, labeled, distributed, and/or advertised in a manner that is inconsistent with the conditions for approval specified in the PMA approval for it.

K) 21 C.F.R. § 820.30 because Conceptus and Bayer failed to establish and maintain procedures for validating the device design, including testing of production units under actual or simulated use conditions, creation of a risk plan, and conducting risk analyses, upon obtaining knowledge of device failures including but not limited to perforation, device migration, and/or device fracture/breakage.

L) 21 C.F.R. § 820.100 because upon obtaining knowledge of device failure modes, Conceptus and Bayer: (1) failed to routinely analyze complaints and other sources of quality data to identify existing and potential causes of nonconforming products or other quality problems and failed to use appropriate statistical methodology to detect recurring quality problems, including but not limited to, complaints of perforation, device migration, and/or device fracture/breakage; (2) failed to investigate the cause of nonconformities relating to product, processes, and the quality system; (3) failed to identify the action(s) needed to correct and prevent recurrence of such nonconforming product and other quality problems; and (4) failed to take any and all Corrective and Preventative Actions ("CAPA") necessary to address non-conformance and other internal quality control issues.

M) 21 C.F.R. § 820.70 because Conceptus and Bayer failed to establish Quality Management Systems ("QMS") procedures to assess potential causes of non-conforming products, including but not limited to device migration, device fracture/breakage, and/or latent manufacturing defects, and other quality problems with the Essure device.

N) 21 C.F.R. § 814.39 because Conceptus and Bayer failed to submit and/or timely submit a PMA supplement and make a labeling change to add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association; such evidence is the thousands of reported and unreported adverse events consisting of serious injuries and pregnancies, by the numerous Essure studies consisting of thousands of women reporting that patients who undergo the Essure procedure are more likely to experience injuries and complications which require or will require surgical intervention or re-operation, and by the over 30,000 unreported complaints contained in Conceptus and Bayer's complaint files.

1033. As a direct and proximate result of Conceptus and Bayer's violations of one or more of the above federal statutory and regulatory standards of care, the Essure device was implanted in Plaintiffs and Plaintiffs were caused to endure a serious injury, as defined in 21 C.F.R. § 803.3.

1034. Plaintiffs were caused to suffer, and will suffer in the future, injuries including, but not limited to pain, suffering, lost wages, disability, disfigurement, legal obligations for hospital, medical, nursing, rehabilitative, and other medical services and treatment.

1035. Conceptus and Bayer failed to act as a reasonably prudent Class III medical device manufacturer, distributor, and/or promoter.

1036. Plaintiffs are not seeking to enforce these federal provisions in this action. Likewise, Plaintiffs are not suing merely because Conceptus and Bayer's conduct violates these provisions. Rather Plaintiffs are alleging that Conceptus and Bayer's conduct that violates these provisions also violates parallel state laws.

1037. Conceptus and Bayer’s violations of the aforementioned federal statutes and regulations establish a *prima facie* case of negligence in tort under state common law.

1038. Thus, for violation of federal law including but not limited to the FDCA, the MDA and relevant regulations which results in an unreasonably dangerous product proximately causing injuries there already exists a money damages remedy under state common law.

1039. Conceptus and Bayer's violations of these federal statutes and regulations caused Plaintiffs' injuries.

1040. Plaintiffs' injuries resulted from an occurrence the laws and regulations were designed to prevent.

1041. Plaintiffs are persons whom these statutes and regulations were meant to protect.

1042. Conceptus and Bayer's violations of these statutes or regulations constitutes negligence per se.

c. <u>THIRD CAUSE OF ACTION</u>

Negligence - Misrepresentation

1043. Plaintiffs repeat and incorporate by reference all other paragraphs of this Petition as if fully set forth herein and further allege as follows:

1044. Specific defects in the Essure device, as specified above in this Petition, rendered it defective and unreasonably dangerous.

1045. Conceptus and Bayer made untrue representations and omitted material information to the FDA, Plaintiffs and Plaintiffs' physicians by sponsoring biased medical trials, reports, and articles that concluded that the risks and dangers of Essure did not exist or were significantly less than the actual dangers.

1046. Had Conceptus and Bayer complied with their duties to the FDA as described under the Medical Device Reporting procedure, 21 C.F.R. § 803, the necessary and resultant actions by the FDA and/or appropriate government agencies, would have precluded the use of Essure.

1047. Plaintiffs and their physicians would not have chosen the Essure procedure as a method of permanent sterilization had they known of the true safety risks related to Essure.

1048. Conceptus and Bayer were negligent in making the untrue misrepresentations and omitting material information because Defendant knew, or had reason to know, of the actual, unreasonable dangers and defects in their Essure device.

1049. Conceptus and Bayer intended to induce Plaintiffs and their physicians to rely on their misrepresentations and omissions to use Essure over the alternative methods of permanent sterilization.

1050. Plaintiffs and their physicians were justified in relying, and did rely, on the misrepresentations and omissions about the safety risks related to Essure in deciding to undergo the Essure procedure for permanent sterilization.

1051. Plaintiffs and Plaintiffs physicians were justified in their reliance on Conceptus and Bayer's representations and marketing. Plaintiffs actually did undergo the Essure implant procedure, which ultimately caused Plaintiffs serious physical injury.

1052. In agreeing to undergo a procedure whereby Essure was implanted, Plaintiff and Plaintiff's physician justifiably relied on such misrepresentations by Conceptus and Bayer. As the direct, producing, proximate and legal cause and result of Conceptus and Bayer's misrepresentations, Plaintiffs have suffered severe physical pain, medical and hospital expenses, pain and suffering, and pecuniary loss.

1053. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

1054. Conceptus and Bayer's conduct, as alleged above, was malicious, oppressive, intentional and/or reckless, outrageous, and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiffs and warrants an award of punitive damages.

d. FOURTH CAUSE OF ACTION

Strict Liability – Failure to Warn

1055. Plaintiffs repeat and incorporate by reference all other paragraphs of this Petition as if fully set forth herein and further alleges as follows:

1056. Conceptus and Bayer designed, formulated, tested, packaged, labeled, produced, created, assembled, advertised, manufactured, sold, distributed, marketed, and promoted Essure, including the Essure devices that were implanted into Plaintiffs.

1057. Conceptus and Bayer at all times herein were medical device manufacturers and subject to the Medical Device Reporting regulations under 21 C.F.R. § 803.

1058. Conceptus and Bayer had a duty to warn the FDA about the dangers of the Essure device, which they knew, or in the exercise of ordinary care, should have known, at the time the Essure device left their control, pursuant to 21 C.F.R. § 803.50.

1059. Conceptus and Bayer did know of these increased risks and serious dangers and breached their duty by failing to warn the FDA of same.

1060. Conceptus and Bayer also had a "continuing obligation" to use "the exercise of reasonable care" in warning of potential dangers under parallel state law duties, which includes warning the FDA of dangers and adverse events associated with the Essure device that were known, or should have been known by Conceptus and Bayer at the time of distribution.

1061. At the time the Essure device left control of Conceptus and Bayer when it was implanted into Plaintiffs, it was unreasonably dangerous due to non-compliance by both companies with the FDCA, and the regulations promulgated pursuant to it, including but not limited to, in one or more of the following ways:

A) 21 C.F.R. § 820.3(z)(x), 21 C.F.R. § 820.22, 21 C.F.R. § 820.5, 21 C.F.R. §820.1(a), 21 C.F.R. § 820.22, 21 C.F.R. § 820.160(a), 21 C.F.R. § 820.198(a) and 21 C.F.R. § 820.170(a) because Conceptus and Bayer failed to comply with the general quality control standards found in these regulations.

B) 21 C.F.R. § 803.50; 21 C.F.R. § 814.80, and 21 U.S.C. § 360i(a), because as discussed in detail above, Conceptus and Bayer failed to report and/or timely report adverse events, including but not limited to, complaints of device migration, device fracture/breakage, perforation, heavy menstrual cycle bleeding, and long-term chronic pain, all of which are serious injuries or may lead to a serious injury because such injuries required Plaintiffs to undergo surgical intervention to prevent further injury and/or may require Plaintiffs to undergo surgical intervention in the future to prevent further injury. Defendants' failure to report such events is evidenced by the 2011 FDA Form 483 and by the fact that there were approximately only 900 MDRs reported to the FDA between November 2002 and October 2011 with the majority of those being reported by the manufacturer, but once the MedWatcher app became available and utilized, over 9,000 MDRs were reported directly to the FDA between October 2013 and December 2015, primarily by women with Essure.

C) 21 C.F.R. § 814.84(b)(2) because as discussed in detail above, Conceptus and Bayer failed to report new clinical investigations and/or scientific studies concerning the Essure device about which Conceptus and Bayer knew or reasonably should have known about, including but not limited to the Cornell study, the article published in the online medical journal Conception, and the eight (8) articles describing 12 cases of Essure abdominal migration published between January 2002 and December 2013 that were never reported to the FDA.

D) 21 C.F.R. § 820.198 because Conceptus and Bayer failed to establish and maintain procedures for implementing corrective and preventative action in response to, *inter alia*, complaints of, but not limited to, device migration, device fracture/breakage, perforation, heavy menstrual cycle bleeding, long-term chronic pain, and other quality problems associated with the Essure device.

E) 21 C.F.R. § 820.198 and 21 C.F.R. § 803.3 because Conceptus and Bayer (1) failed to appropriately respond to adverse incident reports, including but not limited to, reports of device migration outside of the fallopian tubes and/or device fracture/breakage, which strongly indicated the Essure device was malfunctioning or otherwise not responding to its Design Objective Intent, which was to remain permanently in Plaintiffs' fallopian tubes, and (2) Conceptus and Bayer continued to sell Essure into the stream of interstate commerce when they knew, or should have known, that the Essure was malfunctioning or otherwise not responding to its Design Objective Intent.

F) 21 U.S.C. §§ 360(q); 360(r) because Conceptus and Bayer created and distributed false and misleading advertising, including but not limited to representations and warranties regarding the risks, safety, recovery time, and effectiveness of Essure in order to convince physicians and patients to use Essure over other methods of permanent birth control, thereby gaining market share.

G) 21 C.F.R. § 814.80 because the Essure device was manufactured, labeled, distributed, and/or advertised in a manner that is inconsistent with the conditions for approval specified in the PMA approval for it.

H) 21 C.F.R. § 820.30 because defendant failed to establish and maintain procedures for validating the device design, including testing of production units under actual or simulated use conditions, creation of a risk plan, and conducting risk analyses, upon obtaining knowledge of device failures including but not limited to perforation, device migration, and/or device fracture/breakage.

I) 21 C.F.R. § 820.100 because upon obtaining knowledge of device failure modes, Conceptus and Bayer: (1) failed to routinely analyze complaints and other sources of quality data to identify existing and potential causes of nonconforming products or other quality problems and failed to use appropriate statistical methodology to detect recurring quality problems, including but not limited to, complaints of perforation, device migration, and/or device fracture/breakage; (2) failed to investigate the cause of nonconformities relating to product, processes, and the quality system; (3) failed to identify the action(s) needed to correct and prevent

recurrence of such nonconforming product and other quality problems; and (4) failed to take any and all Corrective and Preventative Actions ("CAPA") necessary to address non-conformance and other internal quality control issues.

J) 21 C.F.R. § 820.70 because Conceptus and Bayer failed to establish Quality Management Systems ("QMS") procedures to assess potential causes of non-conforming products, including but not limited to device migration, device fracture/breakage, and/or latent manufacturing defects, and other quality problems with the Essure device.

K) 21 U.S.C. § 352(a) because Conceptus and Bayer promoted for the sale of misbranded and adulterated products because the Essure label is false and misleading because Essure is not a safer and more effective method of permanent sterilization than alternative methods, evidenced by the over 10,000 reported adverse events consisting of serious injuries and pregnancies, by the numerous Essure studies consisting of thousands of women reporting that patients who undergo the Essure procedure are more likely to experience injuries and complications which require or will require surgical intervention or re-operation, and by the over 30,000 unreported complaints contained in Conceptus and Bayer's complaint files.

L) 21 U.S.C. § 352(q) because Conceptus and Bayer created and distributed false and misleading advertising for Essure which is a "Restricted Device" because Essure is not a safer and more effective method of permanent sterilization than alternative methods, evidenced by the over 10,000 reported adverse events consisting of serious injuries and pregnancies, by the numerous Essure studies consisting of thousands of women reporting that patients who undergo the Essure procedure are more likely to experience injuries and complications which require or will require surgical intervention or re-operation, and by the over 30,000 unreported complaints contained in Conceptus and Bayer's complaint files.

M) 21 C.F.R. § 814.39 because Conceptus and Bayer failed to submit and/or timely submit a PMA supplement and make a labeling change to add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association; such evidence is the thousands of reported and unreported adverse events consisting of serious injuries and pregnancies, by the numerous Essure studies consisting of thousands of women reporting that patients who undergo the Essure procedure are more likely to experience injuries and complications which require or will require surgical intervention or re-operation, and by the over 30,000 unreported complaints contained in Conceptus and Bayer's complaint files.

1062. As a direct and proximate result of Conceptus and Bayer's violations of one or more of the above federal statutory and regulatory standards of care, the Essure device was implanted in Plaintiffs and Plaintiffs were caused to endure a serious injury, as defined in 21 C.F.R. § 803.3.

1063. Plaintiffs were caused to suffer, and will suffer in the future, injuries including, but not limited to pain, suffering, lost wages, disability, disfigurement, legal obligations for hospital, medical, nursing, rehabilitative, and other medical services and treatment.

1064. Conceptus and Bayer failed to act as a reasonably prudent Class III medical device manufacturer, distributor, and/or promoter.

1065. Plaintiffs are not seeking to enforce these provisions in this action. Likewise, Plaintiffs are not suing merely because Conceptus and Bayer's conduct violates these provisions. Rather

Plaintiffs are alleging that Conceptus and Bayer's conduct that violates these provisions also violates parallel state laws which exist independently of federal law.

1066. Conceptus and Bayer's violations of the aforementioned federal statutes and regulations establish a prima facie case of strict liability in tort under state common law.

1067. Conceptus and Bayer also had a parallel and identical state duty to warn a third party such as the FDA, of the dangers and adverse events associated with the Essure device by reporting such events to the FDA.

1068. Conceptus and Bayer's federal and state duties are parallel and are essentially identical because both duties required Conceptus and Bayer to take the same action in order to assure the safe and effective use of Essure. Both duties required not only that serious adverse events be reported to third parties, but also that Conceptus and Bayer investigate such events and determine the root cause of such events.

1069. Under Missouri law and other applicable state law, Conceptus and Bayer had a duty to warn third parties, such as the FDA, pursuant to the Restatement 2d of Torts § 388 (1965).[104] Comment n provides that,

> a supplier's duty to warn is discharged by providing information about the product's dangerous propensities *to a third person upon whom it can reasonably rely to communicate the information to the ultimate users of the product* or those who may be exposed to its hazardous effects. Restatement (2d) of Torts § 388 cmt. (n).[105]

1070. Thus, for violations of federal law, including the FDCA, the MDA, and regulations promulgated thereunder which results in an unreasonably dangerous product proximately causing injuries, there already exists a money damages remedy under state common law.

1071. The warnings accompanying the Essure device did not adequately warn Plaintiffs and Plaintiffs' physicians, in light of Conceptus and Bayer's scientific and medical knowledge at the time, of the increased risks and serious dangers associated with the Essure device, including but not limited to persistent and chronic pain, severe cramping, long menstrual cycles (polymenorrhea), heavy bleeding (menorrhagia) necessitating medication and/or additional surgical procedures, painful intercourse (dyspareunia), allergic reactions (including but not limited to rashes, itching, abdominal bloating, swelling, headaches, tooth-loss, and hair loss), autoimmune disorders, hysterectomy, salpingectomy, loss of libido, severe long lasting migraines, organ

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[104] *See, e.g.*, *Donahue v. Phillips Petroleum*, 866 F.2d 1008 (8th Cir. 1984) (citing *Morris v. Shell Oil Co*., 467 S.W.2d 39, 42 (Mo. 1971) (adopting comment n of the Restatement 2d of Torts § 388).

[105] Emphasis added. *See also McLaughlin v. Bayer Corp*., 2016 U.S. Dist. LEXIS 37516,*85 (E.D. Pa. Mar. 22, 2016).

perforation, coil migration, coils becoming embedded in other tissues and organs, coil fracture/breakage, coil expulsion, chronic fatigue, pregnancy, excessive weight gain, and poorer global outcomes than alternative options.

1072. In direct violation of 21 C.F.R. § 803.50 as well as State regulations and/or common law, Conceptus and Bayer either recklessly or intentionally minimized and/or downplayed the risks of serious side effects related to Essure when reporting to the FDA, including but not limited to these risks of persistent and chronic pain, severe cramping, long menstrual cycles (polymenorrhea), heavy bleeding (menorrhagia) necessitating medication and/or additional surgical procedures, painful intercourse (dyspareunia), allergic reactions (including but not limited to rashes, itching, abdominal bloating, swelling, headaches, tooth-loss, and hair loss), autoimmune disorders, hysterectomy, salpingectomy, loss of libido, severe long lasting migraines, organ perforation, coil migration, coils becoming embedded in other tissues and organs, coil fracture/breakage, coil expulsion, chronic fatigue, pregnancy, excessive weight gain, and poorer global outcomes than alternative options.

1073. The FDA was unaware of Conceptus and Bayer's omissions and this led to Plaintiffs and Plaintiffs' physicians' reliance on Conceptus and Bayer's inadequate warnings in deciding to use Essure.

1074. Plaintiffs and Plaintiffs' physicians' did not and could not know of the specific increased risks and serious dangers of Essure, and/or were misled by Conceptus and Bayer, who knew of or should have known of the true risks and dangers of Essure based on the number of complaints reported directly to them as well as the reports in the medical and scientific literature that they knew or should have known about.

1075. Conceptus and Bayer consciously chose not to inform the FDA, thereby preventing Plaintiffs and Plaintiffs' physicians' from having the information necessary to make an informed decision when deciding to recommend and undergo the Essure procedure.

1076. The FDA publishes adverse events and MDRs in a public, searchable database called MAUDE and updates the report monthly with all reports received prior to the update.[106] The general public, including physicians and patients, may use the MAUDE database to obtain safety data on medical devices. For example, Dr. Dhruva, et. al published a study in the New England Journal of Medicine entitled *Revisiting Essure – Toward Safe and Effective Sterilization*, which

[106] *See* http:// www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMATJDE/search.cfm.

assessed the safety and effectiveness of Essure. This study was based in part on a search and analysis of the MAUDE database.[107] The study concluded that the increase in reported Essure related adverse event complaints since mid 2013 led the FDA to update Essure's patient label in 2014 to include information about risks of chronic pelvic pain and device migration into the lower abdomen and pelvis, and led to the FDA's decision to reconvene its Obstetrics and Gynecology Devices Panel to reassess Essure's safety and effectiveness on September 24, 2015.

1077. Similarly, a study published in November 2013 in The Journal of Minimally Invasive Gynecology entitled *Analysis of Adverse Events With Essure Hysteroscopic Sterilization Reported to the Manufacturer and User Facility Device Experience Database*, utilized the FDA's MAUDE database.[108] The study objective stated that the MAUDE database is useful for clinicians using an FDA approved medical device to identify the occurrence of adverse events and complications. The study analyzed and investigated reports associated with the Essure hysteroscopic sterilization system using the MAUDE database.

1078. If Conceptus and Bayer had met their duties under federal law and parallel state law, the FDA would have had the information necessary to warn the public, including Plaintiffs and Plaintiffs' physicians, of the increased risks and serious dangers associated with Essure in time to have lessened or prevent Plaintiffs' injuries.

1079. Additionally, if Conceptus and Bayer had met their duty under 21 C.F.R. § 803.50, such information would have been made available to Plaintiffs and Plaintiffs' treating physician, which would have allowed Plaintiffs' treating physician to properly and/or timely diagnose the cause of Plaintiffs' health problems.

1080. As a direct and proximate result of one or more of the above listed dangerous conditions and defects, and of Defendants' failure to provide adequate warnings about them, as required under 21 C.F.R. § 803.50, Plaintiffs sustained serious injuries of a personal and pecuniary nature.

1081. Plaintiffs have sustained extreme pain, suffering, and anguish from the date of Plaintiffs' Essure implant procedure until present and have otherwise suffered serious injuries and damages.

1082. Conceptus and Bayer's conduct, as alleged above, was malicious, oppressive, intentional and/or reckless, outrageous, and constituted willful and wanton disregard for the rights

[107] *See* "Revisiting Essure — Toward Safe and Effective Sterilization," available at: http://www.nejm.org/doi/pdf/10.1056/NEJMp1510514.
[108] *See* "Analysis of Adverse Events With Essure Hysteroscopic Sterilization Reported to the Manufacturer and User Facility Device Experience Database," available at: http://www.jmig.org/article/S1553-4650(13)00281-1/fulltext

or safety of others. Such conduct was directed specifically at Plaintiffs and warrants an award of punitive damages.

e. FIFTH CAUSE OF ACTION

Strict Liability – Manufacturing Defect

1083. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

1084. A manufacturing defect cause of action is a claim that the product sold to the plaintiff was defective because it deviated from the original design and in its defective condition it caused the Plaintiffs injuries.

1085. The original design for a Class III medical device is the product that is approved by the FDA. This FDA approval includes not only the physical components of the product, but the labeling and intended use of the product as well.

1086. Under federal regulations, a product that does not comply with the FDA approval is considered "adulterated" and/or "misbranded." Under state law, a product that does not comply with the FDA approval is considered a "manufacturing defect." Therefore, any product sold that is not incompliance with the FDA approval is both misbranded and/or adulterated under federal law and a manufacturing defect under State common law. Therefore, the same underlying defect and/or actions of the manufacturer that have given rise to a federal violation are also a parallel state violation.

1087. There are multiple manufacturing defects in the Essure device that were implanted into Plaintiffs which caused Plaintiffs' device to migrate and/or break/fracture apart and/or caused Plaintiffs to experience heavy menstrual cycle bleeding and long-term chronic pain amongst other side effects, all which became known to Conceptus and Bayer, including but not limited to:

A) The stainless steel used in the device became unpassivated, which can cause the device to rust;

B) the nitinol could have a nickel rich oxide which the body attacks;

C) the no lead solder could in fact have trace lead in it;

D) the Galvanic action between the metals used to manufacture Essure, which causes the encapsulation of the product within the fallopian tubes, could be a continuous irritant to some patients;

E) the nitinol in the device can degrade due to High Nickel Ion release, increasing the toxicity of the product for patients;

F) latent manufacturing defects such as cracks, scratches, and other disruption of the smooth surface of the metal coil, may have existed in the finished product, causing excess nickel to leach into the surrounding tissues after implantation;

G) PET fibers degrade at 65 degrees, therefore considerable degradation is expected at 98 degrees in the human body and degradation products of the PET used in the implant can be toxic to patients, inciting both chronic inflammation and possible autoimmune issues;

H) the mucosal immune response to nickel is different than the immune response in non-mucosal areas of the body;

I) there was an inadequate solder joint between the inner and outer coils of the micro-insert which can cause the micro-insert to fracture/break apart, and which Conceptus and Bayer admit is or could be a reason for device breakage, and;

J) the central axis was not fully adhered to the spring which can cause the micro-insert to fracture/break apart, and which Conceptus and Bayer admit is or could be a reason for device breakage.

1088. As part of the FDA approval, a manufacturer must abide by general reporting requirements that are included in the conditions for approval. These conditions include reporting to the FDA any adverse events or new scientific findings about the product that are later learned of. The failure to do so violates the FDA approval. Given the nature of the information that is required to be reported in the conditions of approval and the relationship of the manufacturer to the FDA and ultimately to the consumer, reporting to the FDA provides reasonable assurance that the information will reach those whose safety depends on their having it. Here, not only did Conceptus and Bayer not report required information, but they actively concealed such relevant safety information from the FDA, the medical community, and consumers, including Plaintiffs and Plaintiffs' physicians.

1089. Conceptus and Bayer further violated federal law in the manufacture of Essure in that they:

A) used non-conforming material;

B) failed to use pre-sterile and post-sterile cages;

C) manufactured Essure at an unlicensed facility;

D) manufactured Essure for three years without a license to do so;

E) failed to analyze or identify existing potential causes of non-conforming product and other quality problems;

F) failed to track the non-conforming product;

G) failed to follow procedures used to control products which did not conform to specifications;

H) failed to have complete Design Failure Analyses; and

I) failed to document CAPA activities for a supplier correction action;

1090. Violating the conditions of approval for the FDA approval is another way of saying that the manufacturer violated the original design of the product and therefore creates a viable manufacturing defect claim.

1091. The Essure device implanted in Plaintiffs were not reasonably safe for their intended uses and were defective as described herein as a matter of law with respect to their manufacture, in that they deviated materially from Conceptus and Bayer's design and manufacturing specifications in such a manner as to pose unreasonable increased risks of serious bodily harm to Plaintiffs.

1092. The Essure devices manufactured and sold by Conceptus and Bayer and implanted into Plaintiffs were defective in manufacture because they did not comply with Conceptus and Bayer's own design specifications, used non-conforming material, and deviated from otherwise identical units from the same product line, manufactured with the same specifications.

1093. At all times mentioned herein, Conceptus and Bayer placed Essure on the market and supplied the Essure device used during Plaintiffs' permanent sterilization procedure.

1094. The Essure device that was implanted in Plaintiffs was promoted, distributed, manufactured and used in a manner that is in violation of federal law, the FDCA, the MDA, and regulations promulgated thereunder.

1095. Conceptus and Bayer have a duty to manufacture the Essure device consistent with the specifications, requirements, federal regulations, PMA, and/or conditions of approval. Conceptus and Bayer breached this duty for the reasons set forth below.

1096. At the time the Essure devices left control of Conceptus and Bayer when it was implanted into Plaintiffs, it was unreasonably dangerous due to non-compliance by both companies

with the FDCA, and the regulations promulgated pursuant to it, including but not limited to, in one or more of the following ways:

A) 21 U.S.C. § 352(a) because Conceptus and Bayer promoted for the sale of misbranded and adulterated products because the Essure label is false and misleading because Essure is not a safer and more effective method of permanent sterilization than alternative methods, evidenced by the over 10,000 reported adverse events consisting of serious injuries and pregnancies, by the numerous Essure studies consisting of thousands of women reporting that patients who undergo the Essure procedure are more likely to experience injuries and complications which require or will require surgical intervention or re-operation, and by the over 30,000 unreported complaints contained in Conceptus and Bayer's complaint files.

B) 21 U.S.C. § 331(a) because Conceptus and Bayer introduced into interstate commerce a medical device that was misbranded, for the reasons set forth herein.

C) 21 U.S.C. § 352(q) because Conceptus and Bayer created and distributed false and misleading advertising for Essure which is a "Restricted Device" because Essure is not a safer and more effective method of permanent sterilization than alternative methods, evidenced by the over 10,000 reported adverse events consisting of serious injuries and pregnancies, by the numerous Essure studies consisting of thousands of women reporting that patients who undergo the Essure procedure are more likely to experience injuries and complications which require or will require surgical intervention or re-operation, and by the over 30,000 unreported complaints contained in Conceptus and Bayer's complaint files.

D) 21 C.F.R. § 820.3(z)(x), 21 C.F.R. § 820.22, 21 C.F.R. § 820.5, 21 C.F.R. §820.1(a), 21 C.F.R. § 820.22, 21 C.F.R. § 820.160(a), 21 C.F.R. § 820.198(a) and 21 C.F.R. § 820.170(a) because Conceptus and Bayer failed to comply with the general quality control standards found in these regulations for the reasons set forth herein.

E) 21 C.F.R. § 803.50; 21 C.F.R. § 814.80, and 21 U.S.C. § 360i(a), because as discussed in detail above, Conceptus and Bayer failed to report and/or timely report adverse events, including but not limited to, complaints of device migration, device fracture/breakage, perforation, heavy menstrual cycle bleeding, and long-term chronic pain, all of which are serious injuries or may lead to a serious injury because such injuries required Plaintiffs to undergo surgical intervention to prevent further injury and/or may require Plaintiffs to undergo surgical intervention in the future to prevent further injury.

F) 21 C.F.R. § 814.84(b)(2) because as discussed in detail above, Conceptus and Bayer failed to report new clinical investigations and/or scientific studies concerning the Essure device about which Conceptus and Bayer knew or reasonably should have known about, including but not limited to the Cornell study, the article published in the online medical journal Conception, and the eight (8) articles describing 12 cases of Essure abdominal migration published between January 2002 and December 2013 that were never reported to the FDA.

G) 21 U.S.C. §§ 360(q); 360(r) because Conceptus and Bayer created and distributed false and misleading advertising, including but not limited to representations and warranties regarding the risks, safety, recovery time, and effectiveness of Essure in order to convince physicians and patients to use Essure over other methods of permanent birth control, thereby gaining market share.

H) 21 C.F.R. § 820.198 because Conceptus and Bayer failed to establish and maintain procedures for implementing corrective and preventative action in response to, *inter alia*, complaints of, but not limited to, device migration, device fracture/breakage, perforation, heavy menstrual cycle bleeding, long-term chronic pain, and other quality problems associated with the Essure device.

I) 21 C.F.R. § 820.198 and 21 C.F.R. § 803.3 because Conceptus and Bayer (1) failed to appropriately respond to adverse incident reports, including but not limited to, reports of device migration outside of the fallopian tubes and/or device fracture/breakage, which strongly indicated the Essure device was malfunctioning or otherwise not responding to its Design Objective Intent, which was to remain permanently in Plaintiffs' fallopian tubes, and (2) Conceptus and Bayer continued to sell Essure into the stream of interstate commerce when they knew, or should have known, that the Essure was malfunctioning or otherwise not responding to its Design Objective Intent.

J) 21 C.F.R. § 814.80 because the Essure device was manufactured, packaged, stored, labeled, distributed, and/or advertised in a manner that is inconsistent with the conditions for approval specified in the PMA approval for it.

K) 21 C.F.R. § 820.30 because Conceptus and Bayer failed to establish and maintain procedures for validating the device design, including testing of production units under actual or simulated use conditions, creation of a risk plan, and conducting risk analyses, upon obtaining knowledge of device failures including but not limited to perforation, device migration, and/or device fracture/breakage.

L) 21 C.F.R. § 820.100 because upon obtaining knowledge of device failure modes, Conceptus and Bayer: (1) failed to routinely analyze complaints and other sources of quality data to identify existing and potential causes of nonconforming products or other quality problems and failed to use appropriate statistical methodology to detect recurring quality problems, including but not limited to, complaints of perforation, device migration, and/or device fracture/breakage; (2) failed to investigate the cause of nonconformities relating to product, processes, and the quality system; (3) failed to identify the action(s) needed to correct and prevent recurrence of such nonconforming product and other quality problems; and (4) failed to take any and all Corrective and Preventative Actions ("CAPA") necessary to address non-conformance and other internal quality control issues.

M) 21 C.F.R. § 820.70 because Conceptus and Bayer failed to establish Quality Management Systems ("QMS") procedures to assess potential causes of non-conforming products, including but not limited to device migration, device fracture/breakage, and/or latent manufacturing defects, and other quality problems with the Essure device.

1097. As a direct and proximate result of Defendants' violations of one or more of the above mentioned federal statutory and regulatory standards of care, Essure was implanted in Plaintiffs and Plaintiffs were caused to endure a serious injury, as defined in 21 C.F.R. § 803.3.

1098. Plaintiffs were caused to suffer, and will suffer in the future, injuries including, but not limited to pain, suffering, lost wages, disability, disfigurement, legal obligations for hospital, medical, nursing, rehabilitative, and other medical services and treatment.

1099. Conceptus and Bayer failed to act as a reasonably prudent Class III medical device manufacturer, distributor, and/or promoter.

1100. Plaintiffs are not seeking to enforce these provisions in this action. Likewise, Plaintiffs are not suing merely because Defendants' conduct violates these provisions. Rather Plaintiffs are alleging that Defendants' conduct that violates these provisions also violates parallel state laws.

1101. Conceptus and Bayer's violations of the aforementioned federal statutes and regulations establish a *prima facie* case of strict liability in tort under state common law.

1102. Thus, for violations of federal law, including, the FDCA, the MDA, and regulations promulgated thereunder which results in an unreasonably dangerous product proximately causing injuries there already exists a money damages remedy under state common law.

1103. At all times herein mentioned, Conceptus and Bayer had specific knowledge of the increased risks involved in the use of Essure.

1104. At all times herein mentioned, the Essure device produced serious side effects, including but not limited to irregular heavy menstrual cycle bleeding, organ perforation, and severe chronic pain which required surgical intervention to remove the Essure coils or will require surgical intervention to remove the Essure coils in the future, and Conceptus and Bayer knew or should have known that said usage could be unsafe because of said side effects.

1105. At all times herein mentioned, Plaintiffs relief upon the misrepresentations of Conceptus and Bayer and used the Essure product as promoted and instructed.

1106. The Essure device, as given to Plaintiffs, was ineffective, defective, and unreasonably dangerous when manufactured, designed, promoted, and instructed by Conceptus and Bayer, who are strictly liable for the injuries arising from its use. The increased risks and dangers attendant to the Essure device greatly outweighed the benefits to be expected from said use as promoted by Conceptus and Bayer

1107. The Essure device failed to perform in a manner that a reasonable consumer would expect it to perform.

1108. By placing Essure on the market and promoting Essure as the safest, most effective permanent sterilization method available, Conceptus and Bayer impliedly represented it was safe for the purpose intended, and intended that doctors and patients in the general public should rely on their misrepresentations. Plaintiffs and Plaintiffs' doctors did rely on each of said misrepresentations and material omissions, all to their damage as hereinabove alleged.

1109. In doing the things aforementioned, Conceptus and Bayer are guilty of malice, oppression, and fraud, and Plaintiffs are therefore entitled to recovery of exemplary or punitive damages in the sum according to proof at trial.

f. SIXTH CAUSE OF ACTION

Common Law Fraud

1110. Plaintiffs repeat and incorporate by reference all other paragraphs of this Petition as if fully set forth herein and further alleges as follows:

1111. Plaintiffs bring a claim against Conceptus and Bayer for knowingly concealing information relative to the Essure device.

1112. Conceptus and Bayer committed fraud by concealing and/or making fraudulent representations during their promotional practices concerning the Essure device.

1113. In connection with the Essure product, Conceptus and Bayer fraudulently and intentionally misrepresented material and important health and safety product risk information from Plaintiff and Plaintiffs' physicians, all as alleged in this Petition. The specifics regarding the content of the misrepresentations, when and where Conceptus and Bayer made them, and to whom they were made, as well as what aspects of the statements were misleading and why, are alleged above in the body of this Petition.

1114. Plaintiff and Plaintiff's physicians would not have decided to use Essure had they known of the real increased risks and dangers related to Essure.

1115. Any of the following is sufficient to independently establish Medtronic's liability for fraudulent misrepresentation and/or fraud:

A) Conceptus and Bayer fraudulently concealed and misrepresented the health and safety hazards, symptoms, constellation of symptoms, diseases and/or health problems associated with Essure;

B) Conceptus and Bayer fraudulently concealed and misrepresented information about the known increased risks and dangers as well as the limited benefits of the use of Essure and the relative benefits and availability of alternate options.

1116. As a medical device manufacturer, Conceptus and Bayer had an affirmative continuing duty to warn the public, including Plaintiff and Plaintiff's physicians regarding the increased risks and dangers they knew, learned, or should have known about associated with Essure.

1117. Had Conceptus and Bayer complied with their duties to the FDA as described under the FDCA, the necessary and resultant actions by the FDA and/or appropriate government agencies would have precluded the use of the product in the surgeries giving rise to all causes of action.

1118. Conceptus and Bayer omitted material adverse information and provided inaccurate, false, or misleading information which was material to treating surgeons' treatment decisions,

which misled surgeons and patients who were relying on those surgeons' professional judgment, including Plaintiffs and their treating surgeons.

1119. Conceptus and Bayer knew that use of Essure was unreasonably dangerous and could lead to serious side effects as listed herein. Conceptus and Bayer failed to take any measures whatsoever to alert surgeons or the public regarding increased risks and dangers and instead to continued to promote the Essure device as safe, and further took action to conceal said information.

1120. When Conceptus and Bayer engaged in this deceptive campaign and made the above representations and/or omissions, they knew those representations and/or omissions to be false, or willfully and wantonly and recklessly disregarded whether the representations and/or omissions were true. These representations and/or omissions were made by Conceptus and Bayer with the intent of defrauding and deceiving the public, including Plaintiffs, Plaintiffs' physicians, and the medical community.

1121. At the time the aforesaid representations and/or omissions were made by Conceptus and Bayer, Plaintiffs and their medical providers were unaware of the falsity of said representations and/or omissions and reasonably relied upon Conceptus and Bayer's assertions, promulgated through aggressive sales tactics as set forth herein, that the Essure device was safe when in fact it was not.

1122. In reliance upon Conceptus and Bayer's representations, each Plaintiff's physician used Essure.

1123. As a direct and proximate result of said misrepresentations and/or material omissions, each Plaintiff's physician used Essure.

1124. Had Plaintiffs' physicians and Plaintiffs been made fully and adequately aware of the inefficacy and serious increased risks and dangers associated with such use, they would not have used it.

1125. Had the FDA known of the actual dangers of and inefficacy of the use of Essure, they would have initiated a recall of the product, dear doctor letter, or safety signal and/or warned the public of the danger.

1126. Conceptus and Bayer's motive in failing to advise surgeons, the public, Plaintiffs, and the FDA of these increased risks was for financial gain and fear that, if they provided proper and adequate information, Essure would lose sales and market share.

1127. Conceptus and Bayer's conduct, as alleged above, was malicious, fraudulent, and oppressive toward Plaintiffs in particular and the public generally, and Conceptus and Bayer conducted themselves in a willful, wanton, and reckless manner by actively violating federal regulations.

1128. Conceptus and Bayer are guilty of malice, oppression, and fraud, and Plaintiffs are therefore entitled to recovery of exemplary or punitive damages in sum according to proof at trial.

g. SEVENTH CAUSE OF ACTION

Constructive Fraud

1129. Plaintiffs repeat and incorporate by reference all other paragraphs of this Petition as if fully set forth herein and further alleges as follows:

1130. Cocneptus and Bayer marketed the Essure device to and for the benefit of Plaintiffs, and marketed it to their physicians, and Conceptus and Bayer knew or had reason to know of the unreasonable dangers and serious defects in Essure, and that Plaintiffs and their physicians would use the product.

1131. Conceptus and Bayer owed Plaintiff a duty to exercise reasonable or ordinary care under the circumstances, in light of the generally recognized and prevailing best scientific knowledge, and to produce and market Essure in as safe a manner and condition as possible.

1132. Specific defects, as specified above in this Petition, in the Essure device rendered it defective and unreasonably dangerous.

1133. Through the conduct described in the foregoing and subsequent paragraphs of this Petition, Conceptus and Bayer breached their duties to Plaintiffs. Such breaches exhibited willful and wanton conduct, and a reckless disregard for the safety of others.

1134. By breaching their duties to Plaintiffs, Conceptus and Bayer gained an advantage by wrongfully profiting from the sale of Essure.

1135. Plaintiffs and their physicians justifiably relied on Conceptus and Bayer's misrepresentations and material concealment of the actual increased risks and dangers of Essure.

1136. As the direct, producing, proximate and legal cause and result of Conceptus and Bayer's breach of their duties, Plaintiffs have suffered severe injuries, great mental and emotional distress, physical pain, pecuniary loss and were otherwise seriously injured and damaged.

1137. As the direct, producing, proximate and legal cause and result of Conceptus and Bayer's breach of their duties, Plaintiffs have been injured and incurred damages, including but not limited to medical and hospital expenses, and pain and suffering.

1138. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

1139. Conceptus and Bayer's conduct, as alleged above, was malicious, oppressive, intentional and/or reckless, outrageous, and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiffs and warrants an award of punitive damages.

h. EIGHT CAUSE OF ACTION

Fraudulent Concealment

1140. Plaintiffs repeat and incorporate by reference all other paragraphs of this Petition as if fully set forth herein and further alleges as follows:

1141. In connection with their Essure device, Conceptus and Bayer fraudulently and intentionally concealed and suppressed material and important health and safety product risk information from the FDA, Plaintiffs, and Plaintiffs' physicians, all as alleged in this Petition. Plaintiffs and Plaintiffs' physician would not have used Essure for permanent sterilization had they known of the increased safety risks and dangers related to Essure.

1142. Either of the following is sufficient to independently establish Conceptus and Bayer's liability for fraudulent concealment:

A) Conceptus and Bayer fraudulently concealed and misrepresented the increased health and safety risks, dangers, hazards, symptoms, constellation of symptoms, diseases and/or health problems associated with the Essure device to physicians, including Plaintiffs' physicians; and

B) Conceptus and Bayer fraudulently concealed and misrepresented material safety information about the known increased risks and dangers of the use of Essure and the relative benefits and availability of alternate procedures.

1143. Conceptus and Bayer knew, or should have known, that they were concealing, suppressing, and misrepresenting true information about the known increased risks and benefits of the use of Essure and the relative benefits and availability of alternate procedures.

1144. Conceptus and Bayer knew that Plaintiffs and Plaintiffs' physicians would regard the matters that they concealed, suppressed, and misrepresented to be important in determining the course of treatment for the Plaintiffs, including Plaintiffs and Plaintiffs' physicians' decision whether or not to use Essure as a method of permanent sterilization.

1145. Conceptus and Bayer intended to cause Plaintiffs and Plaintiffs' physicians to rely on their concealment of material safety information, suppression, and misrepresentations about the increased risks and dangers related to Essure as a method of permanent sterilization.

1146. Plaintiffs and Plaintiffs' physicians were justified in relying, and did rely, on Conceptus and Bayer's concealment of information and misrepresentations about the increased safety risks and dangers related to Essure in deciding to recommend and choose the Essure procedure for permanent sterilization.

1147. As a direct and proximate result of Conceptus and Bayer's fraudulent concealment, suppression, and misrepresentations of material increased health and safety risks and dangers relating to Essure and Conceptus and Bayer's promotion and marketing practices, Plaintiffs suffered injuries and economic loss, and Plaintiffs will continue to suffer injuries, damages and economic loss.

1148. As the direct, proximate, and legal cause and result of Conceptus and Bayer's false and deceptive marketing and promotion practices related to Essure, Plaintiffs have been injured and have incurred damages, including but not limited to medical and hospital expenses, physical and mental pain and suffering, and loss of the enjoyment of life.

1149. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

1150. Conceptus and Bayer's conduct, as alleged above, was malicious, oppressive, intentional and/or reckless, outrageous, and constituted willful and wanton disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiffs and warrants an award of punitive damages.

i. NINTH CAUSE OF ACTION

Breach of Express Warranty

1151. Plaintiffs repeat and incorporate by reference all other paragraphs of this Petition as if fully set forth herein and further alleges as follows:

1152. Conceptus and Bayer utilized journal articles, advertising media, and sales representatives to promote, encourage, and urge the use and purchase of the Essure device, representing the quality to health care professionals, the FDA, Plaintiffs, and the public in such a way as to induce its purchase or use, thereby making an express warranty that Essure would conform to the representations. More specifically, Conceptus and Bayer represented that Essure was safe and effective, that it was safe and effective for use by individuals such as Plaintiffs, and/or that it was safer and more effective than alternative methods of permanent sterilization.

1153. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

1154. Essure did not conform to the representations made by Conceptus and Bayer, as the Essure device was not safe and effective and was not safe and effective for use by individuals such as Plaintiffs.

1155. At all relevant times, Plaintiffs used Essure for the purpose and in the manner intended by Conceptus and Bayer.

1156. Plaintiffs and Plaintiffs' physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its hidden increased risks and its unreasonable dangers.

1157. Defendants' breaches constitute violations of state common laws, including but not limited to, the following statutory provisions as applicable:

1158. Ala. Code §§ 7-2-313, 7-2-314 (2013); Alaska St. § 45.02.313 (effective 2013); Ariz. Rev. Stat. Ann. § 47-2313 (2013); Ark. Code Ann. § 4-2-313 (2013); Cal. U. Com. Code § 2313(1) (2013); Cal. Civ. Code §1791.2(a) (2013); Co. Rev. St. § 4-2-316 (2013); Conn. Gen. Stat. Ann. § 42a-2-313 (effective 2013); 6 Del. C. § 2-313 (2013); D.C. Code Ann. § 28:2-313 (2013); Fla. Stat. Ann. § 672.313 (2013); O.C.G.A. § 11-2-318 (2013); Haw. Rev. Stat. § 490:2-313 (2013); Id. Code § 28-2-314(2)(c) (2013); Ill. Comp. Stat. Ann. Ch. 810, 5/2-313 (2013); Ind. Code Ann. § 26-1-2-313 (2013); Iowa Code Ann. § 554.2313 (2013); Kans. Stat. Ann. § 84-2-313 (2013); KRS § 355.2-318 (2013); Kan. Stat. Ann. § 60-3302(c)(2013); Ky. Rev. Stat. § 355.2-318 (2013); La. Rev. Stat. §§ 9:2800.54, 9:2800.58 (2013); Me. Rev. Stat. Ann. tit. 11, § 2-314 and 2-315 (2013); 14 M.R.S. § 221 (2013); Md. Code Ann., Com. Law § 2-318 (2013); Mass. M.G.L. c. 106,

§ 2-313 (2013); Mich. Comp. Laws Ann. § 440.2313 (2013); Minn. Stat. Ann. § 336.2-313 through 315 (2013); Miss. Code Ann. § 11-1-63(i)(3) and 75-2-313 (2013); Mo. Rev. Stat. Ann. § 400.2-313 (2013); Mont. Code Ann. § 30-2-313 (2013); Neb. Rev. Stat. U.C.C. § 2-313 et seq. (2012); Nev. Rev. Stat. U.C.C. § 104.2313, et seq. (2012); Nev. Rev. Stat. §§ 104.2312-104.2318(2012); N.H. Rev. Stat. Ann. § 382-A:2-313, et seq. (2013); N.M. Stat. Ann. §§ 55-2-313 to -318 (2013); see also UJI 13-1428 to 1433 NRMA; N.Y. U.C.C. Law 2-313, et seq. (2013); N.C. Gen. Stat. Ann. § 25-2-313, et seq. (2013); N.D. Cent. Code § 41-02-30, et seq. (2013); Ohio Rev. Code Ann. § 1302.26, et seq. (2013); Okla. Stat. tit. 12A, § 2-313 et seq. (2013); Or. Rev. Stat. § 72.3130, et seq. (2013); 13 Pa. Stat. Ann. § 2313, et seq. (2013); R.I. Gen. Laws § 6A-2 (2013); S.C. Code. Ann. § 36-2-313, et seq. (2012); S.D. Stat. 57A-2-313, et seq. (2013); Tenn. Code Ann. § 47-2-313, et seq. (2013); Tex. Bus. & Com. Code Ann. § 2.313, et seq. (2013); Ut. Code Ann. § 70A-2-313, et seq. (2013); Va. Code Ann. § 8.2-318, et seq. (2013); Vt. Stat. Ann. tit. 9A, § 2-313, et seq. (2013); Wa. Rev. Code § 62A.2-108, et seq. (2013); § 7.72.030(2) (2013); W.Va. Code § 46A-6-108, et seq. (2013); Wis. Stat. Ann. § 402.313, et seq. (2013); and Wyo. Stat. § 34.1-2-313 through 315 (2013).

1159. The breach of the warranty was a substantial factor in bringing about Plaintiffs' injuries. As a direct and proximate result of Conceptus and Bayer's acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, promotion, and distribution of the Essure device, Plaintiff was implanted with Essure and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, pain and suffering, and mental and emotional distress for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

j. TENTH CAUSE OF ACTION

Breach of Implied Warranty

1160. Plaintiffs repeat and incorporate by reference all other paragraphs of this Petition as if fully set forth herein and further alleges as follows:

1161. Essure was not reasonably fit for the ordinary purposes for which such goods are used and did not meet the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manner. Nor was Essure minimally safe for its expected purpose.

1162. At all relevant times, Plaintiffs used Essure for the purpose and in the manner intended by Conceptus and Bayer.

1163. Plaintiffs and Plaintiffs' physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

1164. The breach of the warranty was a substantial factor in bringing about Plaintiffs' injuries.

1165. Conceptus and Bayer breached their implied warranty to Plaintiffs in that Essure was not of merchantible quality, safe and fit for its intended use, or adequately tested, in violation of State Common Law principles and the following statutory provisions as applicable:

1166. Ala. Code §§ 7-2-314, et seq. (2013); Alaska. Stat. §§ 45.02.314, et seq. (2013); Ariz. Rev. Stat. Ann. §§ 47-2314, et seq. (2013); Ark. Code Ann. §§ 4-2-314, et seq. (2013); Cal. Uniform Comm. Code §§ 2314, e2315; Cal. Civ. Code §§ 1791.1(b), 1792.1, and 1792.2(2013); Colo. Rev. Stat. §§ 4-2-316, et seq. (2013); Conn. Gen. Stat. Ann. §§ 42a-2-314, et seq. (2013); Del. Code Ann. tit. 6, §§ 2-314, et seq. (2013); D.C. Code Ann. §§ 28:2-314, et seq. (2013); Fla. Stat. Ann. §§ 672.314, et seq. (2013); O.C.G.A. §§ 11-2-318, et seq. (2013); Haw. Rev. Stat. §§ 490:2-314, et seq. (2013); Idaho Code § 28-2-314(2)(c) (2013); Ill. Comp. Stat. Ann. Ch. 810, 5/2-314, et seq. (2013); Indiana Code Ann. §§ 26-1-2-314, et seq. (2013); Iowa Code Ann. §§ 554.2314, et seq. (2013); Kan. Stat. Ann. §§ 84-2-314, et seq. (2013); KRS § 355.2-318 (2013); Kan. Stat. Ann. § 60-3302(c) (2013); Ky. Rev. Stat. Ann. §§ 355.2-318 (2013), et seq.; La. Civ. Code Ann. art. 9:2800:58, et seq. (2013) and is liable for redhibition under this statute; Me. Rev. Stat. Ann. tit. 11, §§ 2-314, et seq. (2013); 14 M.R.S. § 221 (2013); Md. Code Ann., Com. Law §§ 2-314, et seq. (2013); Mass. M.G.L. c. 106, § 2-314 (2013); Mich. Comp. Laws Ann. §§ 440.2314, et seq. (2013); Minn. Stat. Ann. §§ 336.2-313 through 315 (2013); Miss. Code Ann. §§ 11-1-63(i)(3) and §§ 75-2-313; 75-2-314 (2013); Mo. Rev. Stat. Ann. §§ 400.2-314, et seq. (2013); Mont. Code Ann. §§ 30-2-314, et seq. (2013); Neb. Rev. Stat. §§ 2-314, et seq. and Common Law (2012); Nev. Rev. Stat. §§ 104.2312-104.2318 (2012); N.H. Rev. Stat. Ann. §§ 382-A:2-314, et seq. (2013); N.J. Stat. Ann. §§ 12A:2-314, et seq. (2013); N.M. Stat. Ann. §§ 55-2-313 to -318 (2013); see also UJI 13-1428 to 1433 NRMA (2013); N.Y. U.C.C. Law §§ 2-314, et seq. (2013); N.C. Gen. Stat. Ann. §§ 25-2-314, et seq. (2013); N.D. Cent. Code §§ 41-02-31, et seq. (2013); Ohio Rev. Code Ann. §§ 1302.27, et seq. (2013); Okla. Stat. tit. 12A, §§ 2-314 et seq. (2013); Or. Rev. Stat. §§ 72.3140, et seq.; 72.3150 (2013); 13 Pa. Stat. Ann. §§ 2314 et seq. (2013); R.I. Gen. Laws §§ 6A-2-314, et seq. (2013); S.C. Code Ann. §§ 36-2-314, et seq. (2012); S.D. Codified

Laws §§ 57A-2-314, et seq. (2013); Tenn. Code Ann. §§ 47-2-314, et seq. (2013); Tex. Bus. & Com. Code Ann. §§ 2.314, et seq. (2013); Utah Code Ann. §§ 70A-2-314, et seq. (2013); Va. Code Ann. §§ 8.2-318, et seq. (2013); Vt. Stat. Ann. §§ 9A-2-314, et seq. (2013); Wash. Rev. Code §§ 62A.2-314, et seq.; § 7.72.030(2) (2013); W.Va. Code §§ 46A-6-108, et seq. (2013); Wis. Stat. Ann. §§ 402.314, et seq. (2013); and Wyo. Stat. Ann. §§ 34.1-2-313 through 315 (2013).

1167. As a direct and proximate result of Conceptus and Bayer's acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, promotion, and distribution of the Essure device, Plaintiff was implanted with Essure and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, pain and suffering, and mental and emotional distress for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

k. ELEVENTH CAUSE OF ACTION

Violation of Consumer Protection Laws

1168. Plaintiffs repeat and incorporate by reference all other paragraphs of this Petition as if fully set forth herein and further alleges as follows:

1169. Plaintiffs purchased and used the Essure device for personal use and thereby suffered ascertainable losses as a result of Conceptus and Bayer's actions in violation of the applicable State consumer protection laws, including but not limited to the following:

1170. Ala. Code §§ 8-19-1 et seq. (2013); Alaska Stat. §§ 45.50.471 et seq. (2013); Ariz. Rev. Stat. Ann. §§ 44-1522 et seq. (2013); Ark. Code Ann. §§ 4-88-101 et seq. (2013); Cal. Civ. Code §§ 1770 et seq. and Cal. Bus. & Prof. Code §§ 17200 et seq. (2013); Colo. Rev. Stat. §§ 6-1-105 et seq. (2013); Conn. Gen. Stat. §§ 42-110a et seq. (2013); Del. Code Ann. tit. 6, §§ 2511 et seq. and §§ 2531 et seq. (2013); D.C. Code Ann. §§ 28-3901 et seq. (2013); Fla. Stat. Ann. §§ 501.201 et seq. (2013); O.C.G.A. §§ 10-1-372 et seq. (2013); Haw. Rev. Stat. §§ 480-1 et seq. (2013); Id. Code Ann. §§ 48-601 et seq. (2013); Ill. Comp. Stat. Ann ch. 815, 505/1 et seq. (2013); Ind. Code Ann. §§ 24-5-0.5-1 et seq. (2013); Iowa Code Ann. §§ 714.16 et seq. (2013); Kan. Stat. Ann. §§ 50-623 et seq. (2013); Ky. Rev. Stat. Ann. §§ 367.170 et seq. (2013); La. Rev. Stat. Ann. §§ 51:1401 et seq. (2012); Me. Rev. Stat. Ann. tit. 5, §§ 205A et seq. (2013); Md. Code Ann., Com. Law §§ 13-101 et seq. (2013); Mass. Gen. Laws Ann. Ch. 93A et seq. (2013); Mich. Comp. Laws §§ 445.901 et seq. (2013); Minn. Stat. §§ 325D.43 et seq. and §§ 325F.67 et seq. (2013); Miss.

Code Ann. §§ 75-24-1 et seq. (2013); Mo. Ann. Stat. §§ 407.010 et seq. (2013); Mont. Code Ann. §§ 30-14-101 et seq. (2013); Neb. Rev. Stat. §§ 59-1601 et seq. (2012); Nev. Rev. Stat. §§ 598.0903 et seq. (2012); N.H. Rev. Stat. Ann. §§ 358-A:1 et seq. (2013); N.M. Stat. Ann. §§ 57-12-1 et seq. (2013); N.Y. Gen. Bus. Law §§ 349 et seq. and §§ 350-e et seq. (2013); N.C. Gen. Stat. §§ 75-1.1 et seq. (2013); N.D. Cent. Code §§ 51-12-01 et seq. and §§ 51-15-01 et seq. (2013); Ohio Rev. Code Ann. §§ 1345.01 et seq. (2013); Okla. Stat. tit. 15 §§ 751 et seq. (2013); Or. Rev. Stat. §§ 646.605 et seq. (2013); 73 Pa. Stat. §§ 201-1 et seq. (2013); R.I. Gen. Laws. §§ 6-13.1-1 et seq. (2013); S.C. Code Ann. §§ 39-5-10 et seq. (2012); S.D. Codified Laws §§ 37-24-1 et seq. (2013); Tenn. Code Ann. §§ 47-18-101 et seq. (2013); Tex. Bus. & Com. Code Ann. §§ 17.41 et seq. (2013); Utah Code Ann. §§ 13-11-1 et seq. (2013); Vt. Stat. Ann. tit. 9, §§ 2451 et seq. (2013); Va. Code Ann. §§ 59.1-196 et seq. (2013); Wash. Rev. Code. §§ 19.86.010 et seq. (2013); W.Va. Code §§ 46A-6-101 et seq. (2013); Wis. Stat. Ann. §§ 100.20 et seq. (2013); and Wyo. Stat. Ann. §§ 40-12-101 et seq. (2013).

1171. Had Conceptus and Bayer not engaged in the deceptive conduct described herein, Plaintiffs physicians could not have used Essure and Plaintiffs would not have purchased and/or paid for Essure and not have incurred related medical costs and injury.

1172. Conceptus and Bayer engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiffs for Essure that would not have been paid had Conceptus and Bayer not engaged in unfair and deceptive conduct.

1173. Conceptus and Bayer engaged in unfair methods of competition or deceptive acts or practice that were proscribed by law, including the following:

A) Representing that good or services have characteristic ingredients, uses, benefits or quantities that they do not have;

B) Advertising goods or services with the intent not to sell them as advertised; and

C) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

1174. Plaintiffs were injured by the cumulative and indivisible nature of Conceptus and Bayer's conduct. The cumulative effect of Conceptus and Bayer's conduct directed at patients, physicians and consumers was to create demand for and sell Essure. Each aspect of Conceptus and Bayer's conduct combined to artificially create sales of Essure.

1175. Conceptus and Bayer had a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Essure product.

1176. Had Conceptus and Bayer not engaged in the deceptive conduct described above, Plaintiffs' physicians would not have used the Essure product and Plaintiffs would not have purchased and/or paid for Essure and would not have incurred related medical costs.

1177. Conceptus and Bayer's deceptive, unconscionable, and fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiffs, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed.

1178. Conceptus and Bayer's actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, trade practices in violation of the state consumer protection statutes listed.

1179. Conceptus and Bayer have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of the above listed consumer fraud statutes.

1180. Under the respective state statutes, including the statute listed above, to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Conceptus and Bayer are the supplier, manufacturer, advertiser, and seller, who is subject to liability under such legislation for unfair, deceptive, fraudulent, and unconscionable consumer sales practices.

1181. Conceptus and Bayer violated the state statutes that were enacted to protect consumers against unfair, deceptive, fraudulent and unconscionable trade practices and false advertising, by knowingly and falsely representing that the Essure product was fit to be used for the purpose for which it was intended, when in fact it was defective and dangerous, and by other acts alleged herein. These representations were made in marketing and promotional materials.

1182. The actions and omissions of Conceptus and Bayer alleged herein are uncured or incurable deceptive acts under the state statutes enacted to protect consumers against unfair, deceptive, fraudulent and unconscionable trade practices and false advertising.

1183. Conceptus and Bayer had actual knowledge of the defective and unreasonably dangerous condition of Essure and failed to take any action to cure such defective and dangerous conditions.

1184. Plaintiffs' physician relied upon Conceptus and Bayer's misrepresentations and material omissions in determining whether to use Essure.

1185. Conceptus and Bayer's deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

1186. Bayer's conduct and acts of unfair competition are ongoing and present a continuing threat of harm to the general public.

1187. By reason of unlawful acts engaged in by Conceptus and Bayer, and as a direct and proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

1188. As a direct and proximate result of Conceptus and Bayer's violations of the state consumer protection laws cited herein, Plaintiffs have sustained economic losses and other damages and are entitled to statutory and compensatory damages in an amount to be proven at trial.

l. TWELFTH CAUSE OF ACTION

Missouri Products Liability Action

1189. Plaintiffs adopt and incorporate by reference all allegations contained in the foregoing paragraphs as though fully set forth herein.

1190. Missouri Revised Statute § 537.760 governs claims or actions brought for personal injury, death or property damage caused by the manufacture, construction, design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging, or labeling of any product.

1191. As used in section 537.760, the term "products liability claim" means a claim or portion of a claim in which the plaintiff seeks relief in the form of damages on a theory that the defendant is strictly liable for such damages because: (1) Conceptus and Bayer, wherever situated in the chain of commerce, transferred a product in the course of their business; and (2) The product was used in a manner reasonably anticipated; and (3) Either or both of the following: (a) The product was then in a defective condition unreasonably dangerous when put to a reasonably anticipated use, and the plaintiff was damaged as a direct result of such defective condition as existed when the product was sold; or (b) The product was then unreasonably dangerous when put to a reasonably anticipated use without knowledge of its characteristics, and the plaintiff was damaged as a direct result of the product being sold without an adequate warning.

1192. Conceptus and Bayer designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, advertised, manufactured, sold, distributed, marketed, and promoted Essure, including the Essure devices that were implanted into Plaintiffs.

1193. As discussed above, Conceptus and Bayer have a continuing duty to monitor their product post-approval and to discover and report to the FDA any complaints about product performance, adverse events, and any health consequences of which they know or should have known about which may be attributable to the product. Conceptus and Bayer also have a continuing duty to provide ongoing warnings and instructions regarding safety hazards associated with the Essure device.

1194. Conceptus and Bayer had a parallel duty under Missouri Revised Statute § 537.760 to exercise reasonable care in warning the public, including Plaintiffs and/or Plaintiffs' physicians, about the dangers of Essure that were known or knowable to Defendants at the time of distribution.

1195. Conceptus and Bayer's failure to adequately and timely report adverse events is a violation of the federal requirements and state law.

1196. Specifically, Conceptus and Bayer breached these duties and violated federal law by and including, *inter alia*:

A) 21 C.F.R. § 820.3(z)(x), 21 C.F.R. § 820.22, 21 C.F.R. § 820.5, 21 C.F.R. §820.1(a), 21 C.F.R. § 820.22, 21 C.F.R. § 820.160(a), 21 C.F.R. § 820.198(a) and 21 C.F.R. § 820.170(a) because Conceptus and Bayer failed to comply with the general quality control standards found in these regulations.

B) 21 C.F.R. § 803.50; 21 C.F.R. § 814.80, and 21 U.S.C. § 360i(a), because as discussed in detail above, Conceptus and Bayer failed to report and/or timely report adverse events, including but not limited to, complaints of device migration, device fracture/breakage, perforation, heavy menstrual cycle bleeding, and long-term chronic pain, all of which are serious injuries or may lead to a serious injury because such injuries required Plaintiffs to undergo surgical intervention to prevent further injury and/or may require Plaintiffs to undergo surgical intervention in the future to prevent further injury. Defendants' failure to report such events is evidenced by the 2011 FDA Form 483 and by the fact that there were approximately only 900 MDRs reported to the FDA between November 2002 and October 2011 with the majority of those being reported by the manufacturer, but once the MedWatcher app became available and utilized, over 9,000 MDRs were reported directly to the FDA between October 2013 and December 2015, primarily by women with Essure.

C) 21 C.F.R. § 814.84(b)(2) because as discussed in detail above, Conceptus and Bayer failed to report new clinical investigations and/or scientific studies concerning the Essure device about which Defendant knew or reasonably should have known about, including but not limited to the Cornell study, the article published in the online medical journal Conception, and the eight (8) articles describing 12 cases of Essure abdominal migration published between January 2002 and December 2013 that were never reported to the FDA.

D) 21 C.F.R. § 820.198 because Conceptus and Bayer failed to establish and maintain procedures for implementing corrective and preventative action in response to, *inter alia*, complaints of, but not limited to, device migration, device

fracture/breakage, perforation, heavy menstrual cycle bleeding, long-term chronic pain, and other quality problems associated with the Essure device.

E) 21 C.F.R. § 820.198 and 21 C.F.R. § 803.3 because Conceptus and Bayer (1) failed to appropriately respond to adverse incident reports, including but not limited to, reports of device migration outside of the fallopian tubes and/or device fracture/breakage, which strongly indicated the Essure device was malfunctioning or otherwise not responding to its Design Objective Intent, which was to remain permanently in Plaintiffs' fallopian tubes, and (2) Conceptus and Bayer continued to sell Essure into the stream of interstate commerce when they knew, or should have known, that the Essure was malfunctioning or otherwise not responding to its Design Objective Intent.

F) 21 U.S.C. §§ 360(q); 360(r) because Conceptus and Bayer created and distributed false and misleading advertising, including but not limited to representations and warranties regarding the risks, safety, recovery time, and effectiveness of Essure in order to convince physicians and patients to use Essure over other methods of permanent birth control, thereby gaining market share.

G) 21 C.F.R. § 814.80 because the Essure device was manufactured, labeled, distributed, and/or advertised in a manner that is inconsistent with the conditions for approval specified in the PMA approval for it.

H) 21 C.F.R. § 820.30 because Conceptus and Bayer failed to establish and maintain procedures for validating the device design, including testing of production units under actual or simulated use conditions, creation of a risk plan, and conducting risk analyses, upon obtaining knowledge of device failures including but not limited to perforation, device migration, and/or device fracture/breakage.

I) 21 C.F.R. § 820.100 because upon obtaining knowledge of device failure modes, Conceptus and Bayer: (1) failed to routinely analyze complaints and other sources of quality data to identify existing and potential causes of nonconforming products or other quality problems and failed to use appropriate statistical methodology to detect recurring quality problems, including but not limited to, complaints of perforation, device migration, and/or device fracture/breakage; (2) failed to investigate the cause of nonconformities relating to product, processes, and the quality system; (3) failed to identify the action(s) needed to correct and prevent recurrence of such nonconforming product and other quality problems; and (4) failed to take any and all Corrective and Preventative Actions ("CAPA") necessary to address non-conformance and other internal quality control issues.

J) 21 C.F.R. § 820.70 because Conceptus and Bayer failed to establish Quality Management Systems ("QMS") procedures to assess potential causes of non-conforming products, including but not limited to device migration, device fracture/breakage, and/or latent manufacturing defects, and other quality problems with the Essure device.

K) 21 U.S.C. § 352(a) because Conceptus and Bayer promoted for the sale of misbranded and adulterated products because the Essure label is false and misleading because Essure is not a safer and more effective method of permanent sterilization than alternative methods, evidenced by the over 10,000 reported adverse events consisting of serious injuries and pregnancies, by the numerous Essure studies consisting of thousands of women reporting that patients who undergo the Essure procedure are more likely to experience injuries and complications which require or will require surgical intervention or re-operation, and by the over 30,000 unreported complaints contained in Conceptus and Bayer's complaint files.

L) 21 U.S.C. § 352(q) because Conceptus and Bayer created and distributed false and misleading advertising for Essure which is a "Restricted Device" because Essure is not a safer and more effective method of permanent sterilization than alternative methods, evidenced by the over 10,000 reported adverse events consisting of

serious injuries and pregnancies, by the numerous Essure studies consisting of thousands of women reporting that patients who undergo the Essure procedure are more likely to experience injuries and complications which require or will require surgical intervention or re-operation, and by the over 30,000 unreported complaints contained in Conceptus and Bayer's complaint files

M) 21 C.F.R. § 814.39 because Conceptus and Bayer failed to submit and/or timely submit a PMA supplement and make a labeling change to add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association; such evidence is the thousands of reported and unreported adverse events consisting of serious injuries and pregnancies, by the numerous Essure studies consisting of thousands of women reporting that patients who undergo the Essure procedure are more likely to experience injuries and complications which require or will require surgical intervention or re-operation, and by the over 30,000 unreported complaints contained in Conceptus and Bayer's complaint files.

1197. If Conceptus and Bayer had met their duties under the above mentioned federal and parallel state laws, the FDA would have had the information necessary to warn the public, including Plaintiffs and Plaintiffs' physicians of the increased risks and serious dangers associated with Essure in time to have lessened or prevent Plaintiffs' injuries, which is evidenced by the fact that the FDA is now mandating a new clinical trial, a "black box" warning, and a patient decision checklist which discuss and warn in detail, the risks of the very same injuries Plaintiffs suffered.

1198. Plaintiffs and Plaintiffs' physicians would not have used and recommended the Essure procedure for permanent sterilization if the FDA had been fully and adequately informed of the material and necessary information to be able to communicate the safety risks related to Essure.

1199. Additionally, if Conceptus and Bayer had met their duty under the above mentioned federal regulations and parallel state laws, such information would have been made available to Plaintiffs and Plaintiffs' treating physician, as discussed above, which would have allowed Plaintiffs' treating physician to properly and/or timely diagnose the cause of Plaintiffs' pain and health problems as being the Essure device.

1200. Since Conceptus and Bayer failed to meet their duty under the above mentioned federal and parallel state laws, Plaintiffs and Plaintiffs' treating physicians did not know and had no reason to know that Essure was causing Plaintiffs' injuries.

1201. As such, Plaintiffs and Plaintiffs' treating physicians could not properly and/or timely diagnose the cause of Plaintiffs' injuries, which caused and/or contributed to Plaintiff(s) having to endure prolonged and unnecessary pain and suffering.

1202. As a direct and proximate result of one or more of the above listed violations, and parallel state laws, Plaintiffs sustained serious injuries of a personal and pecuniary nature.

m. <u>THIRTEENTH CAUSE OF ACTION</u>

Violation of the Missouri Merchandising Practices Act

1203. Plaintiffs adopt and incorporate by reference all allegations contained in the foregoing paragraphs as though fully set forth herein.

1204. The Missouri Merchandising Practices Act ("MMPA"), Mo. Ann. Stat. §407.020 provides, in part, as follows:

> The act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce…in or from the state of Missouri, is declared to be an unlawful practice…Any act, use or employment declared unlawful by this subsection violates this subsection whether committed before, during or after the sale, advertisement or solicitation.

1205. At all relevant times and as described herein, Conceptus and Bayer knowingly directly and indirectly represented to the FDA, to Plaintiffs, and to Plaintiffs' physicians that the Essure device was a safe and effective method of permanent birth control when compared to other alternatives, and that when used, it was not defective.

1206. Conceptus and Bayer's advertising, promotions, and representations contained therein were false and misleading and constituted unfair or deceptive acts and practices declared unlawful by the MMPA. Conceptus and Bayer knowingly made false representations for the purpose of deceiving the FDA, Plaintiffs, and Plaintiffs' physicians regarding the safety and efficacy of Essure in order to ensure the marketability and success of Essure, which was in violation of the MMPA.

1207. Had Conceptus and Bayer disclosed the true facts concerning the increased risks and damages they knew or should have known to be associated with Essure, the FDA would have required Conceptus and Bayer to amplify its warning label earlier than February 2016, which would have lessened or prevented Plaintiffs injuries because Plaintiffs' physicians and Plaintiffs would not have chosen to recommend and undergo the Essure procedure.

1208. Conceptus and Bayer engaged in the unlawful practices set forth in this Petition in the sale of merchandise in trade or commerce.

1209. Conceptus and Bayer's concealment, misrepresentations and/or omissions as set forth in this Petition are material in that they relate to matters which are important to consumers or are

likely to affect the purchasing decisions or conduct of consumers, including Plaintiffs' regarding Essure.

1210. Conceptus and Bayer engaged in the concealment, suppression, misrepresentations and/or omission of the aforementioned material facts with the intent that others, such as the FDA, Plaintiffs, their physicians, and/or the general public would rely upon the concealment, suppression, misrepresentation and/or omission of such material facts and purchase Essure.

1211. The concealment, suppression, misrepresentation and/or omission of the aforementioned material facts had the capacity to, was reasonably foreseeable that it would, and did so deceive.

1212. Plaintiffs' physicians would not have used Essure in Plaintiffs and Plaintiffs would not have agreed to undergo the Essure procedure absent the concealment, suppression, or omission of the aforementioned material facts.

1213. Plaintiffs suffered actual and ascertainable loss of money and damages as an actual and proximate result of Defendants' intentional misrepresentation and concealment of material facts.

1214. Conceptus and Bayer's conduct described herein actually and proximately caused Plaintiffs to suffer damages as described throughout this Petition.

1215. Plaintiffs are entitled to recover their actual damages, attorneys' fees, and other equitable relief, pursuant to Missouri law, including Mo. Ann. Stat. § 407.025.

1216. Furthermore, Conceptus and Bayer's unlawful conduct set forth in this Petition was and is wanton, willful and outrageous, and manifests a reckless disregard for the consequences of their actions and for the rights of Plaintiffs and warrants an award of punitive damages to deter Conceptus and Bayer, and others in similar circumstances, from committing such actions in the future.

n. FOURTEENTH CAUSE OF ACTION

Gross Negligence/Punitive Damages

1217. Plaintiff incorporates by reference all other paragraphs of this Petition as if fully set forth herein and further alleges as follows:

1218. At all relevant times herein, Conceptus and Bayer:

A) knew or should have known that Essure was dangerous and ineffective;

B) concealed the dangers and health risks from Plaintiff, physicians, other medical providers, the FDA, and the public at large;

C) attempted to misrepresent and did knowingly make misrepresentations to Plaintiff, her physicians, hospitals, and other medical providers, and the public in general as previously stated herein as to the safety and efficacy of Essure; and

D) with full knowledge of the health risks associated with Essure and without adequate warnings of the same, manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold Essure for use.

1219. Conceptus and Bayer, by and through its officers, directors, managing agents, authorized sales representatives, employees and/or other agents who engaged in malicious, fraudulent and oppressive conduct towards Plaintiff and the public, acted with willful, wanton, conscious, and/or reckless disregard for the safety of Plaintiff and the general public.

1220. Conceptus and Bayer's misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety of Essure. Conceptus and Bayer's conduct was willful, wanton, and undertaken with a disregard for Plaintiff’s rights.

1221. Notwithstanding the foregoing, Conceptus and Bayer continued to market Essure to consumers, including Plaintiff herein, without disclosing the risks.

1222. Conceptus and Bayer knew of Essure’s lack of warnings, but intentionally concealed and/or recklessly failed to disclose that risk and continued to market, distribute, and sell Essure without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff herein, in conscious and/or negligent disregard of the foreseeable harm caused by Essure.

1223. Conceptus and Bayer's intentional and/or reckless failure to disclose information deprived Plaintiff of necessary information to enable her to weigh the true risks of using Essure against its benefits.

1224. As a direct and proximate result of one or more of these wrongful acts or omissions of Conceptus and Bayer, Plaintiff suffered profound injuries that required medical treatment and incurred medical and hospital expenses, for which Plaintiff has become liable.

1225. Conceptus and Bayer are liable jointly and/or severally for all general, special and compensatory damages and equitable relief to which Plaintiff is entitled by law. Plaintiff seeks actual and punitive damages from Conceptus and Bayer and alleges that the conduct of Conceptus and Bayer was committed with knowing, conscious, careless, reckless, willful, wanton, deliberate, and grossly negligent disregard for the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

1226. Conceptus and Bayer have engaged in conduct entitling Plaintiffs to an award of punitive damages pursuant to State Common Law principles including but not limited to the following statutory provisions as applicable:

1227. Ala. Code §§ 6-11-20 (2013); Alaska Stat. § 09.17.020(b) (2013); Ark. Code Ann. § 4-2-313; § 16-55-206 (2013); Cal. Civ. Code §§ 1770 et seq. and Cal. Civ. Code § 3294; Cal. U. Com. Code §§ 2314-2315(2013); Colo. Rev. Stat. § 13-21-102 (2013); Conn. Gen. Stat. §§ 52-240b et seq. (2013); Del. Code Ann. tit. 6, §§ 6855 et seq. (2013); Fla. Stat. Ann. §§ 768.72 (2013); O.C.G.A. §§ 51-12-5.1 (2013); Idaho Code § 6-1601(9); § 6-1604 (2013); Ill. Comp. Stat. Ann ch. 735, 5/2-604.1 (2013); Ind. Code Ann. §§ 34-51-3 et seq. (2013); Iowa Code Ann. § 668A.1 (2013); Kan. Stat. Ann. §§ 60-3702(a) and (e) (2013); Ky. Common Law (2013); Mass. Gen. Laws Ann. c. 229, § 2; M.G.L. c. 93A, § 9(3) (2013); Mich. Comp. Laws (2013); Minn. Stat. Ann. § 549.191; § 549.20, subd.1(a); § 549.20, subd. 4 (2013); Mo. Rev. Stat. § 510.265 (2013); Mont. Code Ann. § 27-1-221(2) (2013); Nev. Rev. Stat. § 42.005 (2012); N.M. Rules Ann. § 13-1827 and UJI 13-861 (2013); N.C. Gen. Stat. §§ 1D-1 et seq. (2013); N.D. Cent. Code §§ 51-12-01 (2013); Ohio Rev. Code Ann. §§ 1345.01 (2013); Okla. Stat. tit. 23 § 9.1 (2013); Or. Rev. Stat. § 30.925 (2013); 73 Pa. Stat. §§ 201-1 et seq. (2013); S.C. Code Ann. §§ 15-33-135 (2013); S.D. Codified Laws (2013); 2011 Tenn. Public Acts ch. 510 (2013); Tex. Civ. Prac. & Rem. Code § 41.001 (2010) et. seq.; Utah Code Ann. § 78B-8-2-3 (2013); and Wis. Stat. Ann. § 895.043 (2013).

1228. Plaintiffs seek actual and punitive damages as alleged herein.

XI. PRAYER FOR RELIEF

1229. WHEREFORE, Plaintiffs and each of them, respectfully demand judgment against Defendants, and each of them, individually, jointly and severally and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

A) compensatory damages to Plaintiffs for past, present, and future damages, including, but not limited to, great pain and suffering and emotional distress and anguish, for severe and permanent personal injuries sustained by Plaintiffs, health and medical care costs, together with interest and costs as provided by law;

B) for all ascertainable economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;

C) for specific damages according to proof;

D) for Punitive and Exemplary damages according to proof;

E) for pre-judgment interest and post-judgment interest as allowed by law;

F) for reasonable attorneys' fees;

G) for the costs of these proceedings; and

H) for such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

1230. Plaintiffs hereby demand a jury trial.

Respectfully submitted,

Date: January 19,, 2017

/s/ Eric D. Holland
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Seth R. Crompton (Mo. Bar #57448)
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Lance C. Unglesby (La. Bar #29690)
Jason R. Williams (La. Bar #25539)
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rarsenault@nbalawfirm.com

Attorneys for Plaintiffs

STATE OF MISSOURI

CITY OF ST. LOUIS

IN THE CIRCUIT COURT OF THE CITY OF ST. LOUIS
STATE OF MISSOURI

LAVETA JORDAN; HEATHER HENK; JANNA LAATU; TYMESHA HUNT; JENNIFER BAGGETT; ASHLEY BAIRD; JESSICA BLAIR; MEAGAN BRADY; DARLA BROWN; CHRISTINE CLARK; CHRISTINE CLARK; AJIKE COATES; EBONY COX; CHERYL DENBOW; DAWN DIAZ; DEZIRE DIAZ; JENNIFER DISCHBEIN; ARLENE DOMINGUEZ; NATAHSA EBARB; NOELLE EDWARDS; STACEY EUELLS; RENEE EWING; SHALEENA FONUA; EUGENIA GALL; NICOLE GARZA; ILIANA GONZALEZ; TERESA GRAHAM; CANDACE GROF; AMY HEAD; SHERRI HELMS; TABATHA HICKS; JAVONDA HILL; TIFFANY HODGES; ANDREA HOGAN; ZENA MOORE HOLLINS; PENNY HOWARD; SHATRICA HOWARD; KRISTIN HUERTA; MARCI HUGHES; KELLY JOHNSON; JENNY JOHNSON; AMBER KAMBER; KIMBERLY KEARN; WENDY KELLEY; AMBER LAPLANT; KRISTIAN LEE; ELIZABETH LITTLE; JESSICA LOUDERMILK; JENNIFER MARECLE; STARLITA MCCALL; MARIAN MCGOWAN; AMY MENDEZ; ROBIN MEYERS; DAWN MIRUKA; JENNIFER MOTT; JANE NAGY; APRIL NEELY; MICHELLE NWANKWO; REGINA O'NEAL; DARYLYNE OSBORNE; LAKESHA OWENS; MELISSA PAGLIARINI; KELLI PARR; CRYSTAL PAXSON; PRINCILLA PEARSON; ASHELY PEEPLES; GRACELYN PRUITT; TIFFANY QUEEN; HILDA RAMIREZ-VILLEGAS; PATRICIA RANDELS; MONICA REINEIR; NANCY RIVERA; VANESSA RIVERA; ASYA RODGERS; ASHLEY ROGERS; TABITHA ROSS; AMY RUTAN; CRISTINA RUVALCABA; SOPHIA SILVA; HOLLIE SLEDGE; JESSICA STRICKLAND; TINA STRICKLAND; AMANDA SULLIVAN; KENESHA THOMAS; MARCELINA TURCIOS; TAMMY WARD; ERICA WARE; NINA WEAVER; FELICIA WEBER; MICHELLE WEEDMAN; LAVENA WILKERSON; MELISSA WILLIAMS; JOHNNIE WILLIAMS; CHARLI ZOVAK	)	CASE NO.: DIVISION NO.: JURY TRIAL DEMAND

Plaintiffs

-vs

BAYER CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC., (F/K/A CONCEPTUS, INC.), BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER A.G

Defendants

PETITION FOR ISSUANCE OF SUMMONSES FOR SERVICE

COME NOW, the above named Plaintiffs by and through their undersigned counsel, and requests this Honorable Court to issue summonses for service upon the named defendants as follows:

BAYER, CORPORATION.
2595 Interstate Drive, Suite 103
Harrisburg, PA 17110

BAYER HEALTHCARE LLC
221 Bolivar Street
Jefferson City, MO 65101

BAYER ESSURE, INC., f/k/a
CONCEPTUS, INC.
2711 Centerville Rd., Suite 400
Wilmington, DE 19808

BAYER HEALTHCARE
PHARMACEUTICALS, INC.
221 Bolivar St.
Jefferson City, MO 65101

BAYER A.G.
Die Prasidentin des Oberlandesgerichts
Dusseldorf Cecilienallee 3
Dusseldorf, Germany 40474

Dated: January 23, 2017

s/ Eric D. Holland
Eric D. Holland - *(Mo. Bar # 39935)*
HOLLAND LAW FIRM, LLC
300 N Tucker, Suite 801
St. Louis, MO 63101
TEL: (314) 241-8111
FAX: (314) 241-5554
Email: eholland@allfela.com

One of the Attorneys for Plaintiffs

1722-CC00173

In the
CIRCUIT COURT
City of St. Louis, Missouri

Laveta Jordan, et al.,
Plaintiff/Petitioner

vs.

Bayer Corporation, et al.,
Defendant/Respondent

For File Stamp Only

January 23, 2017
Date

Case number

Division

REQUEST FOR APPOINTMENT OF PROCESS SERVER

Comes now Plaintiffs (Requesting Party), pursuant to Local Rule 14, requests the appointment by the Circuit Clerk of

Name of Process Server	Address	Telephone
Bob Thomure/Metro One Investigations	PO Box 23008, St Louis, MO 63156	314-533-0010

to serve the summons and petition in this cause on the below named parties.

SERVE:
Bayer Corporation
Name
2595 Interstate Dr., Suite 103
Address
Harrisburg, PA 1711
City/State/Zip

SERVE:
Bayer Healthcare LLC
Name
221 Bolivar Street
Address
Jefferson City, MO 65101
City/State/Zip

SERVE:
Bayer Essure, Inc., f/k/a Conceptus, Inc.
Name
2711 Centerville Rd., Suite 400
Address
Wilmington, DE 19808
City/State/Zip

SERVE:
Bayer Healthcare Pharmaceuticals, Inc.
Name
221 Bolivar St.
Address
Jefferson City, MO 65101
City/State/Zip

FURTHER, PLEASE SEE ATTACHED EXHIBIT A

Appointed as requested:
TOM KLOEPPINGER, Circuit Clerk

By_____
Deputy Clerk

Date

Eric D. Holland
Attorney/Plaintiff/Petitioner
39335
Bar No.
300 N Tucker Blvd Suite 801 St Louis MO 63101
Address
314-241-8111
Phone No.

RULE 14 SPECIAL PROCESS SERVERS

1. Any person appointed by the Court or the Circuit Clerk to serve process must have a license issued pursuant to this rule to serve process.

2. Licenses to serve process shall be issued by the Sheriff of the City of St. Louis if the applicant has met the following qualifications:

   a. Is twenty-one years of age or older;

   b. Has a high school diploma or an equivalent level of education;

   c. Has insurance coverage for any errors or omissions occurring in the service of process;

   d. Has not been convicted, pleaded guilty to or been found guilty of any felony, or of any misdemeanor involving moral turpitude; and,

   e. Has passed a training course for the service of process which shall be administered by the Sheriff of the City of St. Louis.

3. Each applicant for a process server license under the provisions of this rule shall provide an affidavit setting forth such person's legal name, current address, any other occupations and current telephone numbers. Licensed process servers shall immediately notify the Sheriff of the City of St. Louis of any change in the above information, and the failure to do so shall constitute good cause for the revocation of such person's license.

4. The Sheriff of the City of St. Louis shall maintain a list of persons licensed to serve process pursuant to this rule, and shall make such list available to litigants upon request.

5. A photo identification card designed by the Sheriff of the City of St. Louis shall be issued in addition to the license. No other identification will be allowed. All licenses must be signed and approved by the Sheriff of the City of St. Louis and the Presiding Judge or his designee.

6. A license fee recommended by the Sheriff and approved by the Court En Banc shall be charged to cover the costs of compiling and maintaining the list of process servers and for the training of such process servers. The license fees shall be made payable to the Sheriff of the City of St. Louis.

7. A license for service of process issued under this rule may be revoked by the Sheriff with the approval of the Presiding Judge or his designee, for any of the following reasons:

   a. Misrepresentation of duty or authority;

   b. Conviction, guilty plea or finding of guilty of any state or federal felony, or a misdemeanor involving moral turpitude;

   c. Improper use of the license;

   d. Making a false return; or

   e. Any other good cause.

   Provided, no service of process made by an appointed process server with a revoked license shall be void if the Court or Circuit Clerk made the appointment in good faith without knowledge of the license revocation.

8. Any person authorized to serve process may carry a concealed firearm as allowed by Section 506.145, RSMo, only while actually engaged in the service of process and only if the person has passed a firearms qualification test approved by a law enforcement agency; provided, however, that any licensed special process server may file a written waiver of the right to carry a concealed firearm and thereby avoid the requirements of firearm training and testing. Any violation of this section shall be considered beyond the scope of the privilege to carry a concealed weapon that is granted by the appointment, and shall constitute good cause for the revocation of the license.

9. Applications for the appointment of a special process server shall be made on forms available in the offices of the Sheriff and Circuit Clerk. Orders Appointing special process servers may list more than one licensed server as alternatives.

10. The licenses granted pursuant to this rule shall be good for two years. Each person granted a license shall be required to reapply at the expiration of the license and shall be required to provide all the information required in the initial application, including a current police record check.

(Approved 9/28/92; amended 11/23/92; 5/31/95; 12/17/07)

EXHIBIT A

Continuation to Request for Appointment of Special Process Server

SERVE:

BAYER A.G.
Die Prasidentin des Oberlandesgerichts
Dusseldorf Cecilienallee 3
Dusseldorf, Germany 40474

1722-CC00173

In the
CIRCUIT COURT
City of St. Louis, Missouri

Laveta Jordan, et al.,
Plaintiff/Petitioner

vs.

Bayer Corporation, et al.,
Defendant/Respondent

January 23, 2017
Date

Case number

Division

For File Stamp Only

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Name of Process Server	Address	Telephone
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2595 Interstate Dr., Suite 103
Address
Harrisburg, PA 1711
City/State/Zip

SERVE:
Bayer Healthcare LLC
Name
221 Bolivar Street
Address
Jefferson City, MO 65101
City/State/Zip

SERVE:
Bayer Essure, Inc., f/k/a Conceptus, Inc.
Name
2711 Centerville Rd., Suite 400
Address
Wilmington, DE 19808
City/State/Zip

SERVE:
Bayer Healthcare Pharmaceuticals, Inc.
Name
221 Bolivar St.
Address
Jefferson City, MO 65101
City/State/Zip

FURTHER, PLEASE SEE ATTACHED EXHIBIT A

Appointed as requested:
TOM KLOEPPINGER, Circuit Clerk

By Michelle McMullen
Deputy Clerk

January 23 2017
Date

Eric D. Holland
Attorney/Plaintiff/Petitioner
39335
Bar No.
300 N Tucker Blvd Suite 801 St Louis MO 63101
Address
314-241-8111
Phone No.

EXHIBIT A

Continuation to Request for Appointment of Special Process Server

SERVE:

BAYER A.G.
Die Prasidentin des Oberlandesgerichts
Dusseldorf Cecilienallee 3
Dusseldorf, Germany 40474

STATE OF MISSOURI

CITY OF ST. LOUIS

IN THE CIRCUIT COURT OF THE CITY OF ST. LOUIS
STATE OF MISSOURI

LAVETA JORDAN; HEATHER HENK; JANNA LAATU; TYMESHA HUNT; JENNIFER BAGGETT; ASHLEY BAIRD; JESSICA BLAIR; MEAGAN BRADY; DARLA BROWN; CHRISTINE CLARK; CHRISTINE CLARK; AJIKE COATES; EBONY COX; CHERYL DENBOW; DAWN DIAZ; DEZIRE DIAZ; JENNIFER DISCHBEIN; ARLENE DOMINGUEZ; NATAHSA EBARB; NOELLE EDWARDS; STACEY EUELLS; RENEE EWING; SHALEENA FONUA; EUGENIA GALL; NICOLE GARZA; ILIANA GONZALEZ; TERESA GRAHAM; CANDACE GROF; AMY HEAD; SHERRI HELMS; TABATHA HICKS; JAVONDA HILL; TIFFANY HODGES; ANDREA HOGAN; ZENA MOORE HOLLINS; PENNY HOWARD; SHATRICA HOWARD; KRISTIN HUERTA; MARCI HUGHES; KELLY JOHNSON; JENNY JOHNSON; AMBER KAMBER; KIMBERLY KEARN; WENDY KELLEY; AMBER LAPLANT; KRISTIAN LEE; ELIZABETH LITTLE; JESSICA LOUDERMILK; JENNIFER MARECLE; STARLITA MCCALL; MARIAN MCGOWAN; AMY MENDEZ; ROBIN MEYERS; DAWN MIRUKA; JENNIFER MOTT; JANE NAGY; APRIL NEELY; MICHELLE NWANKWO; REGINA O'NEAL; DARYLYNE OSBORNE; LAKESHA OWENS; MELISSA PAGLIARINI; KELLI PARR; CRYSTAL PAXSON; PRINCILLA PEARSON; ASHELY PEEPLES; GRACELYN PRUITT; TIFFANY QUEEN; HILDA RAMIREZ-VILLEGAS; PATRICIA RANDELS; MONICA REINEIR; NANCY RIVERA; VANESSA RIVERA; ASYA RODGERS; ASHLEY ROGERS; TABITHA ROSS; AMY RUTAN; CRISTINA RUVALCABA; SOPHIA SILVA; HOLLIE SLEDGE; JESSICA STRICKLAND; TINA STRICKLAND; AMANDA SULLIVAN; KENESHA THOMAS; MARCELINA TURCIOS; TAMMY WARD; ERICA WARE; NINA WEAVER; FELICIA WEBER; MICHELLE WEEDMAN; LAVENA WILKERSON; MELISSA WILLIAMS; JOHNNIE WILLIAMS; CHARLI ZOVAK	)	CASE NO.: DIVISION NO.: JURY TRIAL DEMAND

Plaintiffs

-vs

BAYER CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC., (F/K/A CONCEPTUS, INC.), BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER A.G

Defendants

ENTRY OF APPEARANCE

COMES NOW, R. Seth Crompton of Holland Law Firm, LLC, and hereby enters his appearance as attorney of record for the named Plaintiffs.

Dated: January 23, 2017

Respectfully submitted,

/s/ R. Seth Crompton
R. Seth Crompton - Bar #: 57448
Holland Law Firm, LLC
300 N. Tucker Blvd., Suite 801
St. Louis, MO 63101
Tel: 314-241-8111
Fax: 314-241-5554
Email: scrompton@allfela.com

CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing was served by e-filing through the Missouri Electronic Filing System on this 23rd day of January, 2017.

/s/ R. Seth Crompton
R. Seth Crompton - Bar #: 57448
Holland Law Firm, LLC
300 N. Tucker Blvd., Suite 801
St. Louis, MO 63101
Tel: 314-241-8111
Fax: 314-241-5554
Email: scrompton@allfela.com

IN THE 22ND JUDICIAL CIRCUIT COURT, CITY OF ST LOUIS, MISSOURI

Judge or Division: MICHAEL KELLAN MULLEN	**Case Number: 1722-CC00173**	BOB THOMURE
Plaintiff/Petitioner: LAVETA JORDAN **vs.**	Plaintiff's/Petitioner's Attorney/Address ERIC D HOLLAND 300 NORTH TUCKER STE 801 SAINT LOUIS, MO 63101	
Defendant/Respondent: BAYER CORPORATION	Court Address: CIVIL COURTS BUILDING 10 N TUCKER BLVD SAINT LOUIS, MO 63101	
Nature of Suit: CC Pers Injury-Prod Liab		(Date File Stamp)

Summons in Civil Case

The State of Missouri to: **BAYER HEALTHCARE LLC**
Alias:

221 BOLIVAR STREET
JEFFERSON CITY, MO 65101

SPECIAL PROCESS SERVER

COURT SEAL OF

CITY OF ST LOUIS

You are summoned to appear before this court and to file your pleading to the petition, a copy of which is attached, and to serve a copy of your pleading upon the attorney for Plaintiff/Petitioner at the above address all within 30 days after receiving this summons, exclusive of the day of service. If you fail to file your pleading, judgment by default may be taken against you for the relief demanded in the petition.

January 23, 2017 Thomas Kloeppinger

Date Clerk

Further Information:

Sheriff's or Server's Return

Note to serving officer: Summons should be returned to the court within thirty days after the date of issue.

I certify that I have served the above summons by: (check one)

☐ delivering a copy of the summons and a copy of the petition to the Defendant/Respondent.

☐ leaving a copy of the summons and a copy of the petition at the dwelling place or usual abode of the Defendant/Respondent with _____ a person of the Defendant's/Respondent's family over the age of 15 years.

☐ (for service on a corporation) delivering a copy of the summons and a copy of the petition to

_____ (name) _____ (title).

☐ other _____.

Served at _____ (address)

in _____ (County/City of St. Louis), MO, on _____ (date) at _____ (time).

_____ _____

Printed Name of Sheriff or Server Signature of Sheriff or Server

Must be sworn before a notary public if not served by an authorized officer:

(Seal)

Subscribed and sworn to before me on _____ (date).

My commission expires: _____ _____

Date Notary Public

Sheriff's Fees

Summons	$_____
Non Est	$_____
Sheriff's Deputy Salary	
Supplemental Surcharge	$ 10.00
Mileage	$_____ (_____ miles @ $._____ per mile)
Total	$_____

A copy of the summons and a copy of the petition must be served on **each** Defendant/Respondent. For methods of service on all classes of suits, see Supreme Court Rule 54.

IN THE 22ND JUDICIAL CIRCUIT COURT, CITY OF ST LOUIS, MISSOURI

Judge or Division: MICHAEL KELLAN MULLEN	**Case Number: 1722-CC00173**	**BOB THOMURE**
Plaintiff/Petitioner: LAVETA JORDAN **vs.**	Plaintiff's/Petitioner's Attorney/Address ERIC D HOLLAND 300 NORTH TUCKER STE 801 SAINT LOUIS, MO 63101	
Defendant/Respondent: BAYER CORPORATION	Court Address: CIVIL COURTS BUILDING 10 N TUCKER BLVD SAINT LOUIS, MO 63101	
Nature of Suit: CC Pers Injury-Prod Liab		(Date File Stamp)

Summons in Civil Case

The State of Missouri to: **BAYER HEALTHCARE PHARMACEUTICALS INC**
Alias:

221 BOLIVAR ST
JEFFERSON CITY, MO 65101

SPECIAL PROCESS SERVER

COURT SEAL OF

CITY OF ST LOUIS

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January 23, 2017 Thomas Kloeppinger

Date Clerk

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☐ leaving a copy of the summons and a copy of the petition at the dwelling place or usual abode of the Defendant/Respondent with _____ a person of the Defendant's/Respondent's family over the age of 15 years.

☐ (for service on a corporation) delivering a copy of the summons and a copy of the petition to

_____ (name) _____ (title).

☐ other _____.

Served at _____ (address)

in _____ (County/City of St. Louis), MO, on _____ (date) at _____ (time).

_____ _____

Printed Name of Sheriff or Server Signature of Sheriff or Server

Must be sworn before a notary public if not served by an authorized officer:

(Seal)

Subscribed and sworn to before me on _____ (date).

My commission expires: _____ _____

Date Notary Public

Sheriff's Fees

Summons	$_____
Non Est	$_____
Sheriff's Deputy Salary	
Supplemental Surcharge	$ 10.00
Mileage	$_____ (_____ miles @ $._____ per mile)
Total	$_____

A copy of the summons and a copy of the petition must be served on **each** Defendant/Respondent. For methods of service on all classes of suits, see Supreme Court Rule 54.

IN THE 22ND JUDICIAL CIRCUIT COURT OF CITY OF ST LOUIS, MISSOURI

Judge or Division: MICHAEL KELLAN MULLEN	**Case Number: 1722-CC00173**	
Plaintiff/Petitioner: LAVETA JORDAN **vs.**	Plaintiff's/Petitioner's Attorney/Address: ERIC D HOLLAND 300 NORTH TUCKER STE 801 SAINT LOUIS, MO 63101	**BOB THOMURE**
Defendant/Respondent: BAYER CORPORATION	Court Address: CIVIL COURTS BUILDING 10 N TUCKER BLVD SAINT LOUIS, MO 63101	
Nature of Suit: CC Pers Injury-Prod Liab		(Date File Stamp)

Summons for Personal Service Outside the State of Missouri
(Except Attachment Action)

The State of Missouri to: BAYER CORPORATION
Alias:

2595 INTERSTATE DRIVE
SUITE 103
HARRISBURG, PA 17110

SPECIAL PROCESS SERVER

COURT SEAL OF
CITY OF ST LOUIS

You are summoned to appear before this court and to file your pleading to the petition, copy of which is attached, and to serve a copy of your pleading upon the attorney for the Plaintiff/Petitioner at the above address all within 30 days after service of this summons upon you, exclusive of the day of service. If you fail to file your pleading, judgment by default will be taken against you for the relief demanded in this action.

January 23, 2017
Date

Thomas Kloeppinger
Circuit Clerk

Further Information:

Officer's or Server's Affidavit of Service

I certify that:

1. I am authorized to serve process in civil actions within the state or territory where the above summons was served.
2. My official title is _____ of _____ County, _____ (state).
3. I have served the above summons by: (check one)
   - ☐ delivering a copy of the summons and a copy of the petition to the Defendant/Respondent.
   - ☐ leaving a copy of the summons and a copy of the petition at the dwelling place or usual abode of the Defendant/Respondent with _____, a person of the Defendant's/Respondent's family over the age of 15 years.
   - ☐ (for service on a corporation) delivering a copy of the summons and a copy of the petition to _____ (name) _____ (title).
   - ☐ other (describe) _____.

Served at _____ (address)
in _____ County, _____ (state), on _____ (date) at _____ (time).

_____ Printed Name of Sheriff or Server

_____ Signature of Sheriff or Server

Subscribed and Sworn To me before this _____ (day) _____ (month) _____ (year)

I am: (check one)
- ☐ the clerk of the court of which affiant is an officer.
- ☐ the judge of the court of which affiant is an officer.
- ☐ authorized to administer oaths in the state in which the affiant served the above summons. (use for out-of-state officer)
- ☐ authorized to administer oaths. (use for court-appointed server)

(Seal)

_____ Signature and Title

Service Fees, if applicable

Summons $_____
Non Est $_____
Mileage $_____ (_____ miles @ $ _____ per mile)
Total $_____

See the following page for directions to clerk and to officer making return on service of summons.

Directions to Clerk

Personal service outside the State of Missouri is permitted only upon certain conditions set forth in Rule 54. The clerk should insert in the summons the names of only the Defendant/Respondent or Defendants/Respondents who are to be personally served by the officer to whom the summons is delivered. The summons should be signed by the clerk or deputy clerk under the seal of the court and a copy of the summons and a copy of the petition for each Defendant/Respondent should be mailed along with the original summons to the officer who is to make service. The copy of the summons may be a carbon or other copy and should be signed and sealed in the same manner as the original but it is unnecessary to certify that the copy is a true copy. The copy of the motion may be a carbon or other copy and should be securely attached to the copy of the summons but need not be certified a true copy. If the Plaintiff's/Petitioner has no attorney, the Plaintiff's/Petitioner's address and telephone number should be stated in the appropriate square on the summons. This form is not for use in attachment actions. (See Rule 54.06, 54.07 and 54.14)

Directions to Officer Making Return on Service of Summons

A copy of the summons and a copy of the motion must be served on each Defendant/Respondent. If any Defendant/Respondent refuses to receive the copy of the summons and motion when offered, the return shall be prepared accordingly so as to show the offer of the officer to deliver the summons and motion and the Defendant's/Respondent's refusal to receive the same.

Service shall be made: (1) On Individual. On an individual, including an infant or incompetent person not having a legally appointed guardian, by delivering a copy of the summons and motion to the individual personally or by leaving a copy of the summons and motion at the individual's dwelling house or usual place of abode with some person of the family over 15 years of age, or by delivering a copy of the summons and petition to an agent authorized by appointment or required by law to receive service of process; (2) On Guardian. On an infant or incompetent person who has a legally appointed guardian, by delivering a copy of the summons and motion to the guardian personally; (3) On Corporation, Partnership or Other Unincorporated Association. On a corporation, partnership or unincorporated association, by delivering a copy of the summons and motion to an officer, partner, or managing or general agent, or by leaving the copies at any business office of the Defendant/Respondent with the person having charge thereof or by delivering copies to its registered agent or to any other agent authorized by appointment or required by law to receive service of process; (4) On Public or Quasi-Public Corporation or Body. Upon a public, municipal, governmental or quasi-public corporation or body in the case of a county, to the mayor or city clerk or city attorney in the case of a city, to the chief executive officer in the case of any public, municipal, governmental, or quasi-public corporation or body or to any person otherwise lawfully so designated.

Service may be made by an officer or deputy authorized by law to serve process in civil actions within the state or territory where such service is made.

Service may be made in any state or territory of the United States. If served in a territory, substitute the word "territory" for the word "state."

The office making the service must swear an affidavit before the clerk, deputy clerk, or judge of the court of which the person is an officer or other person authorized to administer oaths. This affidavit must state the time, place, and manner of service, the official character of the affiant, and the affiant's authority to serve process in civil actions within the state or territory where service is made.

Service must not be made less than ten days nor more than 30 days from the date the Defendant/Respondent is to appear in court. The return should be made promptly and in any event so that it will reach the Missouri Court within 30 days after service.

IN THE 22ND JUDICIAL CIRCUIT COURT OF CITY OF ST LOUIS, MISSOURI

Judge or Division: MICHAEL KELLAN MULLEN	**Case Number: 1722-CC00173**	
Plaintiff/Petitioner: LAVETA JORDAN **vs.**	Plaintiff's/Petitioner's Attorney/Address: ERIC D HOLLAND 300 NORTH TUCKER STE 801 SAINT LOUIS, MO 63101	**BOB THOMURE**
Defendant/Respondent: BAYER CORPORATION	Court Address: CIVIL COURTS BUILDING 10 N TUCKER BLVD SAINT LOUIS, MO 63101	
Nature of Suit: CC Pers Injury-Prod Liab		(Date File Stamp)

Summons for Personal Service Outside the State of Missouri
(Except Attachment Action)

The State of Missouri to: BAYER ESSURE INC.
Alias: FKA CONCEPTUS INC
2711 CENTERVILLE ROAD
SUITE 400
WILMINGTON, DE 19808

SPECIAL PROCESS SERVER

COURT SEAL OF
CITY OF ST LOUIS

You are summoned to appear before this court and to file your pleading to the petition, copy of which is attached, and to serve a copy of your pleading upon the attorney for the Plaintiff/Petitioner at the above address all within 30 days after service of this summons upon you, exclusive of the day of service. If you fail to file your pleading, judgment by default will be taken against you for the relief demanded in this action.

January 23, 2017
Date

Thomas Kloeppinger
Circuit Clerk

Further Information:

Officer's or Server's Affidavit of Service

I certify that:

1. I am authorized to serve process in civil actions within the state or territory where the above summons was served.
2. My official title is _____ of _____ County, _____ (state).
3. I have served the above summons by: (check one)
   - ☐ delivering a copy of the summons and a copy of the petition to the Defendant/Respondent.
   - ☐ leaving a copy of the summons and a copy of the petition at the dwelling place or usual abode of the Defendant/Respondent with _____, a person of the Defendant's/Respondent's family over the age of 15 years.
   - ☐ (for service on a corporation) delivering a copy of the summons and a copy of the petition to _____ (name) _____ (title).
   - ☐ other (describe) _____.

Served at _____ (address)
in _____ County, _____ (state), on _____ (date) at _____ (time).

_____ Printed Name of Sheriff or Server

_____ Signature of Sheriff or Server

Subscribed and Sworn To me before this _____ (day) _____ (month) _____ (year)

I am: (check one)
- ☐ the clerk of the court of which affiant is an officer.
- ☐ the judge of the court of which affiant is an officer.
- ☐ authorized to administer oaths in the state in which the affiant served the above summons. (use for out-of-state officer)
- ☐ authorized to administer oaths. (use for court-appointed server)

(Seal)

_____ Signature and Title

Service Fees, if applicable

Summons	$_____
Non Est	$_____
Mileage	$_____ (_____ miles @ $ _____ per mile)
Total	$_____

See the following page for directions to clerk and to officer making return on service of summons.

Directions to Clerk

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A copy of the summons and a copy of the motion must be served on each Defendant/Respondent. If any Defendant/Respondent refuses to receive the copy of the summons and motion when offered, the return shall be prepared accordingly so as to show the offer of the officer to deliver the summons and motion and the Defendant's/Respondent's refusal to receive the same.

Service shall be made: (1) On Individual. On an individual, including an infant or incompetent person not having a legally appointed guardian, by delivering a copy of the summons and motion to the individual personally or by leaving a copy of the summons and motion at the individual's dwelling house or usual place of abode with some person of the family over 15 years of age, or by delivering a copy of the summons and petition to an agent authorized by appointment or required by law to receive service of process; (2) On Guardian. On an infant or incompetent person who has a legally appointed guardian, by delivering a copy of the summons and motion to the guardian personally; (3) On Corporation, Partnership or Other Unincorporated Association. On a corporation, partnership or unincorporated association, by delivering a copy of the summons and motion to an officer, partner, or managing or general agent, or by leaving the copies at any business office of the Defendant/Respondent with the person having charge thereof or by delivering copies to its registered agent or to any other agent authorized by appointment or required by law to receive service of process; (4) On Public or Quasi-Public Corporation or Body. Upon a public, municipal, governmental or quasi-public corporation or body in the case of a county, to the mayor or city clerk or city attorney in the case of a city, to the chief executive officer in the case of any public, municipal, governmental, or quasi-public corporation or body or to any person otherwise lawfully so designated.

Service may be made by an officer or deputy authorized by law to serve process in civil actions within the state or territory where such service is made.

Service may be made in any state or territory of the United States. If served in a territory, substitute the word "territory" for the word "state."

The office making the service must swear an affidavit before the clerk, deputy clerk, or judge of the court of which the person is an officer or other person authorized to administer oaths. This affidavit must state the time, place, and manner of service, the official character of the affiant, and the affiant's authority to serve process in civil actions within the state or territory where service is made.

Service must not be made less than ten days nor more than 30 days from the date the Defendant/Respondent is to appear in court. The return should be made promptly and in any event so that it will reach the Missouri Court within 30 days after service.

IN THE 22ND JUDICIAL CIRCUIT COURT OF CITY OF ST LOUIS, MISSOURI

Judge or Division: MICHAEL KELLAN MULLEN	**Case Number: 1722-CC00173**	
Plaintiff/Petitioner: LAVETA JORDAN **vs.**	Plaintiff's/Petitioner's Attorney/Address: ERIC D HOLLAND 300 NORTH TUCKER STE 801 SAINT LOUIS, MO 63101	**BOB THOMURE**
Defendant/Respondent: BAYER CORPORATION	Court Address: CIVIL COURTS BUILDING 10 N TUCKER BLVD SAINT LOUIS, MO 63101	
Nature of Suit: CC Pers Injury-Prod Liab		(Date File Stamp)

Summons for Personal Service Outside the State of Missouri
(Except Attachment Action)

The State of Missouri to: BAYER AG
Alias:
DIE PRASIDENTIN DES OBERLANDES
DUSSELDORF CECILIENALLE 3
DUSSELDORF GERMANY, 40474

SPECIAL PROCESS SERVER

COURT SEAL OF
CITY OF ST LOUIS

You are summoned to appear before this court and to file your pleading to the petition, copy of which is attached, and to serve a copy of your pleading upon the attorney for the Plaintiff/Petitioner at the above address all within 30 days after service of this summons upon you, exclusive of the day of service. If you fail to file your pleading, judgment by default will be taken against you for the relief demanded in this action.

January 23, 2017
Date

Thomas Kloeppinger
Circuit Clerk

Further Information:

Officer's or Server's Affidavit of Service

I certify that:

1. I am authorized to serve process in civil actions within the state or territory where the above summons was served.
2. My official title is _____ of _____ County, _____ (state).
3. I have served the above summons by: (check one)
   - ☐ delivering a copy of the summons and a copy of the petition to the Defendant/Respondent.
   - ☐ leaving a copy of the summons and a copy of the petition at the dwelling place or usual abode of the Defendant/Respondent with _____, a person of the Defendant's/Respondent's family over the age of 15 years.
   - ☐ (for service on a corporation) delivering a copy of the summons and a copy of the petition to _____ (name) _____ (title).
   - ☐ other (describe) _____.

Served at _____ (address)
in _____ County, _____ (state), on _____ (date) at _____ (time).

_____ Printed Name of Sheriff or Server

_____ Signature of Sheriff or Server

Subscribed and Sworn To me before this _____ (day) _____ (month) _____ (year)

I am: (check one)
- ☐ the clerk of the court of which affiant is an officer.
- ☐ the judge of the court of which affiant is an officer.
- ☐ authorized to administer oaths in the state in which the affiant served the above summons. (use for out-of-state officer)
- ☐ authorized to administer oaths. (use for court-appointed server)

(Seal)

_____ Signature and Title

Service Fees, if applicable

Summons $_____
Non Est $_____
Mileage $_____ (_____ miles @ $ _____ per mile)
Total $_____

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Service may be made in any state or territory of the United States. If served in a territory, substitute the word "territory" for the word "state."

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Service must not be made less than ten days nor more than 30 days from the date the Defendant/Respondent is to appear in court. The return should be made promptly and in any event so that it will reach the Missouri Court within 30 days after service.

IN THE 22ND JUDICIAL CIRCUIT COURT, CITY OF ST LOUIS, MISSOURI

Judge or Division: MICHAEL KELLAN MULLEN	**Case Number: 1722-CC00173**	**BOB THOMURE**
Plaintiff/Petitioner: LAVETA JORDAN vs.	Plaintiff's/Petitioner's Attorney/Address ERIC D HOLLAND 300 NORTH TUCKER STE 801 SAINT LOUIS, MO 63101	
Defendant/Respondent: BAYER CORPORATION	Court Address: CIVIL COURTS BUILDING 10 N TUCKER BLVD SAINT LOUIS, MO 63101	
Nature of Suit: CC Pers Injury-Prod Liab		(Date File Stamp)

Summons in Civil Case

The State of Missouri to: **BAYER HEALTHCARE PHARMACEUTICALS INC**
Alias:

221 BOLIVAR ST
JEFFERSON CITY, MO 65101

SPECIAL PROCESS SERVER

COURT SEAL OF
CITY OF ST LOUIS

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January 23, 2017 Thomas Klepplinger
Date Clerk

Further Information:

Sheriff's or Server's Return

Note to serving officer: Summons should be returned to the court within thirty days after the date of issue.

I certify that I have served the above summons by: (check one)

☐ delivering a copy of the summons and a copy of the petition to the Defendant/Respondent.

☐ leaving a copy of the summons and a copy of the petition at the dwelling place or usual abode of the Defendant/Respondent with _____ a person of the Defendant's/Respondent's family over the age of 15 years.

☑ (for service on a corporation) delivering a copy of the summons and a copy of the petition to Lauren Shipley (name) Processor (title).

☐ other _____.

Served at 221 Bolivar # 347, Jefferson City, MO 65101 (address)
in Cole (County/City of St. Louis), MO, on 7TH February, 2017 (date) at 1:15pm (time).

Robert P. Thomure
Printed Name of ~~Sheriff~~ or Server

Robert P. Thomure
Signature of ~~Sheriff~~ or Server

Must be sworn before a notary public if not served by an authorized officer:

(Seal)

Subscribed and sworn to before me on Feb 8, 2017 (date).

My commission expires: 11-12-2018 Robert P. Thomure
Date Notary Public

Sheriff's Fees

Summons	$_____
Non Est	$_____
Sheriff's Deputy Salary	
Supplemental Surcharge	$ 10.00
Mileage	$_____ (_____ miles @ $._____ per mile)
Total	$_____

A copy of the summons and a copy of the petition must be served on **each** Defendant/Respondent. For methods of service on all classes of suits, see Supreme Court Rule 54.

IN THE 22ND JUDICIAL CIRCUIT COURT, CITY OF ST LOUIS, MISSOURI

Judge or Division: MICHAEL KELLAN MULLEN	**Case Number: 1722-CC00173**	BOB THOMURE
Plaintiff/Petitioner: LAVETA JORDAN vs.	Plaintiff's/Petitioner's Attorney/Address ERIC D HOLLAND 300 NORTH TUCKER STE 801 SAINT LOUIS, MO 63101	
Defendant/Respondent: BAYER CORPORATION	Court Address: CIVIL COURTS BUILDING 10 N TUCKER BLVD SAINT LOUIS, MO 63101	
Nature of Suit: CC Pers Injury-Prod Liab		(Date File Stamp)

Summons in Civil Case

The State of Missouri to: **BAYER HEALTHCARE LLC**
Alias:

221 BOLIVAR STREET
JEFFERSON CITY, MO 65101

SPECIAL PROCESS SERVER

COURT SEAL OF
CITY OF ST LOUIS

You are summoned to appear before this court and to file your pleading to the petition, a copy of which is attached, and to serve a copy of your pleading upon the attorney for Plaintiff/Petitioner at the above address all within 30 days after receiving this summons, exclusive of the day of service. If you fail to file your pleading, judgment by default may be taken against you for the relief demanded in the petition.

January 23, 2017 Thomas Kloeppinger
Date Clerk

Further Information:

Sheriff's or Server's Return

Note to serving officer: Summons should be returned to the court within thirty days after the date of issue.

I certify that I have served the above summons by: (check one)

☐ delivering a copy of the summons and a copy of the petition to the Defendant/Respondent.

☐ leaving a copy of the summons and a copy of the petition at the dwelling place or usual abode of the Defendant/Respondent with _____ a person of the Defendant's/Respondent's family over the age of 15 years.

☑ (for service on a corporation) delivering a copy of the summons and a copy of the petition to Lauren Shipley (name) Processor (title).

☐ other _____.

Served at 221 Bolivar St. #347 Jefferson City, Mo 65101 (address)
in Cole County (County/~~City of St. Louis~~), MO, on 7th Feb, 2017 (date) at 1:15pm (time).

Robert P. Thomure
Printed Name of ~~Sheriff or~~ Server

Robert P. Thomure
Signature of ~~Sheriff~~ or Server

Must be sworn before a notary public if not served by an authorized officer:

(Seal)

Subscribed and sworn to before me on Feb. 8, 2017 (date).

My commission expires: 11-12-2018
Date

Notary Public

ROBERT L. THOMURE
Notary Public - Notary Seal
State of Missouri, St Louis County
Commission # 14426906
My Commission Expires Nov 12, 2018

Sheriff's Fees

Summons	$_____
Non Est	$_____
Sheriff's Deputy Salary	
Supplemental Surcharge	$ 10.00
Mileage	$_____ (_____ miles @ $._____ per mile)
Total	$_____

A copy of the summons and a copy of the petition must be served on **each** Defendant/Respondent. For methods of service on all classes of suits, see Supreme Court Rule 54.

IN THE 22ND JUDICIAL CIRCUIT COURT OF CITY OF ST LOUIS, MISSOURI

Judge or Division: MICHAEL KELLAN MULLEN	**Case Number: 1722-CC00173**	
Plaintiff/Petitioner: LAVETA JORDAN vs.	Plaintiff's/Petitioner's Attorney/Address: ERIC D HOLLAND 300 NORTH TUCKER STE 801 SAINT LOUIS, MO 63101	**BOB THOMURE**
Defendant/Respondent: BAYER CORPORATION	Court Address: CIVIL COURTS BUILDING 10 N TUCKER BLVD SAINT LOUIS, MO 63101	
Nature of Suit: CC Pers Injury-Prod Liab		(Date File Stamp)

Summons for Personal Service Outside the State of Missouri
(Except Attachment Action)

The State of Missouri to: **BAYER CORPORATION**
Alias:

2595 INTERSTATE DRIVE
SUITE 103
HARRISBURG, PA 17110

SPECIAL PROCESS SERVER

COURT SEAL OF
CITY OF ST LOUIS

You are summoned to appear before this court and to file your pleading to the petition, copy of which is attached, and to serve a copy of your pleading upon the attorney for the Plaintiff/Petitioner at the above address all within 30 days after service of this summons upon you, exclusive of the day of service. If you fail to file your pleading, judgment by default will be taken against you for the relief demanded in this action.

January 23, 2017
Date

Thomas Kloeppinger
Thomas Kloeppinger
Circuit Clerk

Further Information:

Officer's or Server's Affidavit of Service

I certify that:

1. I am authorized to serve process in civil actions within the state or territory where the above summons was served.
2. My official title is Process Server of Dauphin County, Pennsylvania (state).
3. I have served the above summons by: (check one)
   - ☐ delivering a copy of the summons and a copy of the petition to the Defendant/Respondent.
   - ☐ leaving a copy of the summons and a copy of the petition at the dwelling place or usual abode of the Defendant/Respondent with _____, a person of the Defendant's/Respondent's family over the age of 15 years.
   - ☒ (for service on a corporation) delivering a copy of the summons and a copy of the petition to Kelvin Clem (name) Customer Service (title).
   - ☐ other (describe) _____.

Served at 2595 Interstate Drive, Suite 103, Harrisburg, PA 17110 (address)
in Dauphin County, Pennsylvania (state), on 02/07/17 (date) at 3:12 PM (time).

Bernard Wojciechowski
Printed Name of Sheriff or Server

Signature of Sheriff or Server

Subscribed and Sworn To me before this 13th (day) February (month) 2017 (year)

I am: (check one)
- ☐ the clerk of the court of which affiant is an officer.
- ☐ the judge of the court of which affiant is an officer.
- ☒ authorized to administer oaths in the state in which the affiant served the above summons. (use for out-of-state officer)
- ☐ authorized to administer oaths. (use for court-appointed server)

COMMONWEALTH OF PENNSYLVANIA
(Seal) NOTARIAL SEAL
Brittany Edcius, Notary Public
Lower Paxton Township, Dauphin County
My commission expires April 11, 2018

Notary Public
Signature and Title

Service Fees, if applicable

Summons	$_____
Non Est	$_____
Mileage	$_____ (_____ miles @ $ _____ per mile)
Total	$_____

See the following page for directions to clerk and to officer making return on service of summons.

IN THE 22ND JUDICIAL CIRCUIT COURT OF CITY OF ST LOUIS, MISSOURI

Judge or Division: MICHAEL KELLAN MULLEN	**Case Number: 1722-CC00173**	
Plaintiff/Petitioner: LAVETA JORDAN vs.	Plaintiff's/Petitioner's Attorney/Address: ERIC D HOLLAND 300 NORTH TUCKER STE 801 SAINT LOUIS, MO 63101	**BOB THOMURE**
Defendant/Respondent: BAYER CORPORATION	Court Address: CIVIL COURTS BUILDING 10 N TUCKER BLVD SAINT LOUIS, MO 63101	
Nature of Suit: CC Pers Injury-Prod Liab		(Date File Stamp)

Summons for Personal Service Outside the State of Missouri
(Except Attachment Action)

The State of Missouri to: **BAYER ESSURE INC.**
Alias: FKA CONCEPTUS INC

2711 CENTERVILLE ROAD
SUITE 400
WILMINGTON, DE 19808

SPECIAL PROCESS SERVER

COURT SEAL OF
CITY OF ST LOUIS

You are summoned to appear before this court and to file your pleading to the petition, copy of which is attached, and to serve a copy of your pleading upon the attorney for the Plaintiff/Petitioner at the above address all within 30 days after service of this summons upon you, exclusive of the day of service. If you fail to file your pleading, judgment by default will be taken against you for the relief demanded in this action.

January 23, 2017
Date

Thomas Kloeppinger
Circuit Clerk

Further Information:

Officer's or Server's Affidavit of Service

I certify that:

1. I am authorized to serve process in civil actions within the state or territory where the above summons was served.
2. My official title is PROCESS SERVER of NEW CASTLE County, DE (state).
3. I have served the above summons by: (check one)
   - ☐ delivering a copy of the summons and a copy of the petition to the Defendant/Respondent.
   - ☐ leaving a copy of the summons and a copy of the petition at the dwelling place or usual abode of the Defendant/Respondent with _____, a person of the Defendant's/Respondent's family over the age of 15 years.
   - ☒ (for service on a corporation) delivering a copy of the summons and a copy of the petition to LYNANNE GARES (name) MANAGING AGENT (title).
   - ☐ other (describe) _____.

Served at 2711 CENTERVILLE ROAD, WILMINGTON (address)
in NEW CASTLE County, DE (state), on 2/7/17 (date) at 12:30pm (time).

KEVIN S. DUNN
Printed Name of Sheriff or Server

Signature of Sheriff or Server

Subscribed and Sworn To me before this 7th (day) FEBRUARY (month) 2017 (year)

I am: (check one)
- ☐ the clerk of the court of which affiant is an officer.
- ☐ the judge of the court of which affiant is an officer.
- ☒ authorized to administer oaths in the state in which the affiant served the above summons. (use for out-of-state officer)
- ☐ authorized to administer oaths. (use for court-appointed server)

DENORRIS ANGELO BRITT
(Seal) NOTARY PUBLIC
STATE OF DELAWARE
My Commission Expires May 16, 2018

Signature and Title

Service Fees, if applicable

Summons	$_____
Non Est	$_____
Mileage	$_____ (_____ miles @ $ _____ per mile)
Total	$_____

See the following page for directions to clerk and to officer making return on service of summons.